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MODERN TRENDS
IN
SURGICAL MATERIALS

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MEMORIAL HOSPITAL AND ST JOHN'S
HOSPITAL, LONDON

LONDON
BUTTERWORTH & CO (Publishers) LTD
1958

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PREFACE

It were happy if we studied nature more in natural things and acted according to nature whose rules are few plain and most reasonable

WILLIAM PENN

In recent years, in the field of the healing art, few developments have been more remarkable than the range and variety of the accessions that have been made to the armamentarium of the surgeon New sutures and ligatures the immense possibilities opened up by the non toxic chemically produced resins, the introduction of new metal alloys and the ever improving auto-grafting, homo-grafting and hetero-grafting techniques—all are enlisted in the aid of human tissues damaged by disease or injury beyond repair which have to be replaced by artificial means

All, however is not gain These synthetic implants no less than the natural pose their own problems and difficulties. No surgeon can penetrate the arcana of human life without a deep sense of the individuality of the organism As Carrel has said " Human beings are not found anywhere in nature There are only individuals " and as well as idiosyncratic reactions the surgeon is too often faced with a lack of exact scientific assessment of the materials he is called upon to use

Perhaps the most valuable feature of the present work is the attempt made in the various departments of surgery with which it deals to bring these materials to the test of exacting scientific methods It is a counsel of perfection to say that the surgeon should know the physical chemical and biological reaction of any material which he proposes to use, and that it should be adequately tested by the manufacturers before it is released for general use The truth of the matter is that there is an ever increasing number of new devices which are inadequately designed and tested and since the manufacturers of surgical materials furnish little or no specification data there is thrown upon the surgeon a heavy moral—and legal—responsibility which he should not be called upon to assume Even as is shown in the chapter on " Natural Materials " so old, tried and tested a material as graded catgut is suspect, seeing that its carefully labelled rate of absorption in muscular tissue is so far an approximation as to be totally unreliable "

Or who would have thought at the present time there was much to be said about so stereotyped a technique as sterilization yet the reader will find in the chapter on this subject much that is new surprising, informative and of practical value

Consider again the question of metal implants from the point of view of their use as a surgical material. Only a very small proportion of the metals known to technology have been tested in the living tissue and while the rapidly developing science of metallurgy is continually presenting the surgeon with new and apparently better alloys, he has little means of assessing their value The only specifications governing the manufacture of metal implants at the present time are still those of the 1945 report of the Fracture Committee of the American College of Surgeons

The reader is referred in the following pages to the outstanding contributions which deal with the use of metals in surgery the metallurgical problems in surgery and the biological and mechanical factors in prosthetic surgery The writers of these have assembled a wealth of detail on a subject of prime importance to every surgeon called upon to undertake the internal fixation of fractures.

Metals and plastics form the basis of arthroplasty and by the use of these materials the surgeon s business is to repair the effects of disease or injury His concern is to know the most suitable materials to employ and what the reactions of the tissues will be to those materials. Always to be kept in mind, as has been said, is the uniqueness of the individual. In dealing with the living organism it is always difficult to predict with certainty the outcome of any surgical procedure no matter what care, skill and good judgment are employed What is essential is that the surgeon should know the chemical, physical and reactive properties of any material which he proposes to use Unfortunately such material is not always adequately tested by the manufacturers before it is released for general use, and the whole idea of the symposium which comprises the present volume is to afford some guidance in the choice of materials.

New ground is broken in the article on Biomechanics. It can be defined as a branch of science which applies the methods and techniques of mechanics to an analysis of the effects of external and internal forces on the human body at rest and in motion under normal and pathological conditions. The study of these strains and stresses adds up to what may be called human engineering. Obviously it is of no great assistance to the amputee to be equipped with the most up-to-date artificial limb if the residual biomechanical power is not capable of operating it efficiently Biomechanics comes to the aid of the surgeon in forecasting what material will be best suited over a period of years to withstand the attrition of constant use, and the stresses consequent upon the replacement of abnormal portions of a tissue

Finally there are the grafts—the preservation and transplantation of integument, blood vessels and of whole organs. Here opens out an immense new field of which no man can discern the limits or gauge the possibilities. To encourage in the living organism that stimulus to repair regeneration and replacement which is part of the natural process must always be the ideal of the surgeon

During the last decade the surgical treatment of aneurysms and permanently occluded blood vessels by diseases such as athero-sclerosis, atheroma or thrombo-angeitis obliterans has been marked by great advances. At the present time these diseased sections of the blood vessels can be excised and replaced by venous or autogenous grafts or even by plastic tubes.

The ability to store homografts and the use of plastic prostheses, has enabled surgeons with the aid of hypothermia and the advances in anaesthetic technique to carry out such feats of surgical skill as operations on the heart and on the arch of the aorta.

Since the pioneer work of Carrel, over 40 years ago great strides have been made in the replacement of cells by cells tissues by tissues and organ by organ Whatever benefits are described in favour of metallic or plastic implants there is always one formidable disadvantage—they can never become part of the body structure because actual fusion is impossible On the other hand, the ideal implant is that which is absorbed by the body a condition which only a graft can fulfill.

There is little doubt that in future years artificial materials will be replaced by natural stored grafts (eye banks are already a commonplace) or fresh grafts though many problems, complex and far reaching, even into the penetralia of the mystery of life itself remain to be solved Even when tissues are compatible their union often does no more than to form not a junction but a scaffolding upon which natural regeneration builds up on the donor tissue

Perhaps nowhere is the intense individuality of the human body displayed to clearer purpose than in a homograft reaction in which grafts transplanted from one body to another are rejected The reaction would seem to be immunological in character—the resistance of the organism not perhaps so much to a foreign body as to alien tissue substance The antigens which provoke it have not yet been defined though recent evidence suggests that they may be akin to the blood group substances.

During the past two years a new mode of immunological response has been discovered the reaction of grafted cells against their host and by taking advantage of the principle of immunological tolerance it has become possible to prevent the homograft reaction Immunological tolerance is a state of specific non-reactivity induced by the introduction of donor cells into an animal when it is immunologically immature, for example the new born The study of the formation of these auto-antibodies is and will be most rewarding, for the establishment of the whole principle of tolerance may result in its providing a general mechanism that will prevent auto-immune reactions The phenomenon of tolerance shows that the "homograft problem" as a surgical problem is soluble in principle The solution in practice is another matter The grafting of part of an organ whole organs, tissues or limbs seems theoretically possible but is still tantalizingly remote

There remains for me to thank all the distinguished authors who have contributed to this work In particular I am indebted to Mr A Lee McGregor my old teacher and chief who has honoured me with his contribution on Abdominal Surgery I venture to say that the authors have opened up wide vistas in their various fields which will well repay exploration. In fact, the whole subject embraced by this book is novel enough to invite research and sufficiently large in its scope to enlist, as here, a further combination of scientific technological and surgical investigation. It could not but result in a great addition to our knowledge of some of the obscurer aspects of surgical practice My thanks are also due to the medical editorial staff of Butterworths the publishers. They have been most patient and understanding especially in regard to the delays and alterations inseparable from the compilation of a composite work of this nature. "Give us the tools," cried a great man "and we will finish the job Give us the right tools says this book in effect, and we will make a better job of what we are doing.

LEON GILLIS

LONDON
1958

consumption of electrons occurs at the other the cathode, then a steady flow of current will be maintained in the wire and in the electrolyte The energy required to drive the current will be supplied by the chemical changes occurring at the liquid metal boundaries A corrosion current created in this way will continue indefinitely until the anodic metal is completely dissolved or until the reaction is stifled by some polarization process. A comprehensive account of the various phenomena which occur when metals corrode has been given by Evans (1946).

Corrosion currents can equally well be caused by differences in the chemical compositions of the liquids wetting different parts of the same metal (provided that the two liquids are in electrolytic contact) An example of this aspect of corrosion which is particularly important in surgery is the changes in the redox potential caused by differences in the oxygen content of the blood. The supply of oxygen bearing blood often varies considerably over different parts of the same metal implant. In extreme cases this may itself cause small corrosion currents.

When a surgeon inserts a piece of metal into human tissue he often requires it to withstand the corrosive attack of the body fluids for several decades without further attention. It is extremely important therefore that due attention should be paid to the factors which can influence the resistance of the metal to corrosion. In particular it should be remembered that the behaviour of a surgical implant depends not only on the metal of which it is made, but also on its environment and the manner in which it is handled. The chemical composition must be selected so that it is inert or passive in body tissues and then the implant must be used and handled in such a manner that the corrosion resistance of the metal is not impaired in any way

II. THE CHOICE OF METALS

E. G C. CLARKE AND J HICKMAN

When selecting a metal for surgical implantation a number of points must be considered. The metal must be one that will remain inert and free from corrosion it should be of low toxicity for tissue cells it must have mechanical properties suited to the purpose for which it is intended and finally it should be readily available and comparatively inexpensive. From a consideration of all these factors it is clear that the ideal metal for implantation has yet to be found Of the metals in surgical use today tantalum, titanium Co-Cr Mo alloys such as Vitallium, and stainless steels of the 18/8/Mo type all have their advocates. None of these however can be said to be perfect they are either too scarce too unworkable, or too prone to cause tissue reaction

Inertness and freedom from corrosion

Only a very small proportion of the metals known to technology have been tested in living tissue From the large number of metallic elements available the metallurgist has produced an almost infinite variety of alloys to meet the exacting needs of industry It is thus conceivable that the ideal metal for implantation is one that has already been produced to serve some specific industrial purpose and of whose existence the surgeon is as yet unaware Moreover its inertness in tissue would have to be established by an extensive series of animal experiments before it could be put to clinical trial Such animal experimentation is laborious

and expensive and although essential as a preliminary to surgical use is clearly too costly to be used as a method of testing the hundreds of alloys available Some simpler technique is therefore needed to establish the suitability of a given metal

The work of Venable and Stuck (1938) and others showed that there was a correlation between the electrochemical properties of a metal and its behaviour in biological fluids Since most of this work has been qualitative rather than quantitative Clarke and Hickman (1951 1953) undertook an investigation into the relation between the electrical potentials of metals and their known behaviour in tissue Starting with the premise that certain metals (for example tantalum platinum) were inert in tissue while others (mild steel copper) underwent gross corrosion they attempted to find a single reproducible value readily measurable *in vitro* that would indicate the behaviour that the metal in question might be expected to show when implanted in living tissue This they believed would enable the more likely metals to be selected from scores of others and submitted to the final test of animal experiment

Anodic back e.m f

It was found that if a current was passed through an electrolytic cell containing serum in which the anode and the cathode were a piece of the test metal and a calomel half cell respectively and if the calculated potential difference due to the *IR* drop across this cell were subtracted from the observed potential difference as measured by a valve potentiometer a figure was obtained which was independent of current over a wide range This value known as the anodic back e m f (ABE) was characteristic for the metal and closely proportional to its observed inertness in tissue.

This anodic back e.m f has been found for a large number of metals (Table I) It will be noted that inert metals such as tantalum (+ 1 650 mV) and platinum (+ 1 450 mV) have high positive potentials while those that corrode readily such as iron (− 500 mV) and magnesium (− 1,500 mV) show large negative values In the case of stainless steels in Table II the relation between ABE and composition is clearly shown the addition of 2–3 per cent of molybdenum increasing the potential by over 100 mV This figure should serve to emphasize the dangers attendant on fastening a plate of one type of steel with screws of another

That this ABE is indeed a measure of inertness in tissue was likewise confirmed when small rods of a number of metals were inserted into the long bones of dogs The animals were destroyed and the implants examined at intervals ranging from 3 months to 1 year after implantation The metals used were tantalum, vitallium (Vinertia) (Cr-Co-Mo) alloy S (Cr-Co-Ni) alloy C (Cr Ni Mo) FMB steel (18Cr 8Ni 2 75Mo) FST steel (18Cr 8Ni) silver and mild steel, a series ranging from the completely inert (+ 1 650 mV) to the very reactive (− 400 mV) The inertness of the metal was judged by noting the loss in weight of the implant, and by assessing the reaction of the surrounding tissue by histological and radiological examination (Hickman 1953 Hickman Clarke and Jennings, 1957 unpublished data) It was thus possible to divide the metals into two main groups The first group included tantalum (+ 1 650 mV) alloy C (+ 880 mV) alloy S (+ 750 mV) Vitallium (Vinertia) (+ 650 mV) and FMB steel (+ 480 mV) With these even after a year the metallic implant was as bright and clean as when inserted and still fitted tightly in its hole No measurable loss of weight had occurred Histological

TABLE I

NON-FERROUS METALS

Metal	*Identification*	*Major constituents*	*Potential millivolts (ABE)*	*Young's modulus*	*Tensile strength (tons per sq. in.)*	*Elongation per cent*	*Hardness DPN*	*Machinability*
Titanium	—	—	+ 3,500	15×10^6	40	12	210	May be difficult
Tantalum	—	—	+ 1,650	27×10^6	22	40	40	Similar to copper
Platinum	—	—	+ 1,450	$21{\cdot}4\times10^6$	8	40	42	"
Gold	—	—	+ 1,000	$11{\cdot}3\times10^6$	8	25	20	"
Cr Ni-Mo alloy	Langalloy "5R"	*Cr 15·5–17·5* Mo 16–18 Fe 4·5–7 W 3·75–4·75 Ni-Balance	*+ 875*	*24·5 × 10*	*36*	*10*	*201–248*	Easily machined
Chromium	—	—	+ 750	24×10^6	*≃40*	*<1*	*175*	Not turned but may be ground
Cr-Co-Mo alloy	Vitallium (Vinertia)	65Cr 30Co 5Mo	+ 650	30×10^6	65	10	300–350	Not easily machined. Usually cast
Zirconium	—	—	+ 320	$13{\cdot}5\times10^6$	30	20	85	Easily machined
Nickel	—	—	+ 200	30×10^6	21	28	64	"
Silver	—	—	+ 110	$10{\cdot}3\times10^6$	9	60	26	Similar to copper
Molybdenum	—	—	− 20	$50{\cdot}2\times10^6$	50–60	5–20	147	Easily machined
Copper	—	—	− 30	$17{\cdot}5\times10^6$	14	*58*	*51*	When pure difficult to machine
Cobalt	—	—	− 350	30×10^6	41	1–2	48	—
Aluminium	—	—	− 600	10×10^6	*6*	*60*	*16–22*	Similar to copper
Magnesium	—	—	− 1,550	$6{\cdot}5\times10^6$	11	5	33	Easy but risk of fire

TABLE II
STEELS

Identification	Manufacturer	Major constituent							Potential millivolts (ABE)	Remarks
		C	Ni	Mo	Mn	Cb	Ti	Cu		
34	Firth-Vickers	18 0	18 0	3 75	80	—	60	2 4	550	
FMB 3T	„	18 0	8 0	3 25	30		30	—	500	
SF 35	United Steel Co.	18 26	8 64	2 73	46	—	—	—	480	All have very good corrosion resistance. The titanium free versions will take better polish
FMB	Firth-Vickers	18 0	8 0	2 75	50	—		—	480	
BB 2A	Brown Bayleys	17 1	11 8	2 10	73	—	25	—	480	
18/8SMo*	American	17 0	10 0	2 4	—	—	—	—	480	
FML	Firth-Vickers	18 0	9 5	1 25	30	—	—	—	470	Not as highly resistant FMB
BBMA	Brown Bayleys	18 0	18 7	2 09	78	56	—	2 03	380	
Weldanka B	„	19 2	10 5	—	67	—	70	—	300	
FDP	Firth-Vickers	18 0	8 0	—	40	—	60	—	300	Will not take a good polish
FST	„	18 0	8 0	—	—	—	—	—	300	Will polish well. But corrosion properties affected by heat treatment
FSL	„	19 0	10 0	—	40	—	—	—	300	Corrosion properties not affected by heat treatment
FCB	„	18 0	10 0	—	40	1 2	—	—	300	Will not take a good polish
DDQ	„	12 5	12 5	—	1 0	—	—	—	250	Deep drawing steel
SF 22	United Steel C	17 98	8 26	045	56	—	32	—	230	As FSL
OBK 1	B L and S R.A.	18 0	7 94	09	5	20	—	—	230	
EMS	Firth-Vickers	18 0	10 0	28	1 6	—	60	—	220	Free machining version of FDP but with lower corrosion resistance
SF 21	United Steel Co.	14 22	11 93	—	59	—	—	—	150	As DDQ
ANKA M	Brown Bayleys	12 2	11 9	—	58	—	—	—	120	
S 80	Firth-Vickers	16 5	2 5	—	20	—	—	—	90	
SF 17	United Steel Co.	17 24	32	—	42	—	—	—	80	
FI 17	Firth-Vickers	17 0	—	—	20	—	—	—	75	
SF 11	United Steel Co	13 10	51	—	47	—	—		50	
FG	Firth-Vickers	13 5	—	—	23	—	—		40	
Tormanc	United Steel Co	045	055	01	1 55	—	—		− 350	
Mild Steel		01	T	—	46	—	—	T	− 480	
Iron		—	—	—	—	—	—	—	− 500	

All these steels have similar mechanical properties that is, Young's Modulus about 13 000 tons per square inch Tensile Strength (1 per cent yield point) about 17 to 18 T.s.i. Vickers Hardness Number about 160 to 180. (Exceptions SF 22 and OBK 1 have less tensile strength and are softer.) They are all ductile. It is necessary to use specialised techniques when machining them, but good results can be obtained.

These steels are easily machined and can be heat treated to obtain very high mechanical strengths, but they have poor corrosion resistance. Very poor corrosion resistance

* The British equivalent 18 8/M

examination revealed the presence of varying amounts of necrotic bone In every case the implant was partially encapsulated with a bony sheath. Radiological examination showed an increase in the density of the surrounding bone and a thickening of the cortex With FST steel (+ 300 mV) the finding was similar except that there was still some reactive tissue and a number of free metallic deposits The second group which included silver (+ 110 mV) and mild steel (− 480 mV) gave very different results Here the implants were loose the silver being dulled and the mild steel grossly corroded There was an appreciable loss in weight in both cases. Considerable bone destruction had taken place and there were deposits of metal in the bone space and in the phagocytic cells

These results confirm the suggestion that the behaviour of a metal in tissue may be predicted from a knowledge of its anodic back EMF If this is over + 300 mV the metal comes in the first of the groups mentioned above it will cause minimal tissue reaction and *ceteris paribus* is probably suitable for clinical use If its ABE is below + 300 mV it comes in the second group it will probably cause considerable bone destruction and should not be used in any circumstances. Stainless steels of the 18/8 type such as FST occupy an intermediate position and are probably better avoided.

Thus the first criterion that must be applied to a metal is that it must have an ABE of over + 300 mV and preferably well over this figure Theoretically it will then remain completely inert None of its ions will pass into solution and it will exert no influence beyond the monolayer where it meets its environment. In practice none of the metals in use today is perfect. Under certain conditions, to be discussed later even the best of them may corrode and give rise to tissue reaction.

Cytotoxicity

The extent of this reaction will depend not only on the weight of metal passing into solution but also on its cytotoxicity This phenomenon has been studied in several ways The cytotoxicity of various metallic chlorides has been found by Verne (1954) who divided them into four groups non toxic (for example, Na Ca) slightly toxic (Fe Al) toxic (Ni, Au) and very toxic (Cd Hg) Ménégaux and Odiette (1936) on the other hand studied the cytotoxicity of the metals themselves by noting the rate of growth of chick embryo fibroblasts and osteoblasts placed in contact with discs of various metals They found that certain metals (for example copper iron) were very toxic, others (zinc silver for instance) showed some toxicity while others, such as gold platinum and certain stainless steels were quite inert. It should be noted that these are only the apparent cytotoxicities of the metals, as only the ions that pass into solution exert any effect. It is interesting to compare these results with those of Verne for " absolute " toxicities cited above Thus iron (which corrodes readily) has a large apparent toxicity though the ion itself is only slightly toxic, whereas gold is devoid of " apparent " toxicity although its ions are much more toxic than those of iron This suggests that the first of the two factors mentioned above is the more important a toxic metal that remains inert will do less damage than a non toxic one that corrodes readily

Care must be taken however in comparing the results of tissue culture experiments with conditions noted in the clinical use of metals For example, although

there is abundant evidence that the use of dissimilar metals in surgery causes severe tissue damage (Key 1946 Cater and Hicks, 1956) Ménégaux and Odiette (1935) found that if they placed "couples" of dissimilar metals in tissue cultures the toxic effect was no greater than would have been caused by each metal singly This apparent discrepancy is probably due to the time factor involved Ménégaux and Odiette recorded the results of their tissue culture experiments after 48 hours while corrosion in surgical implants may not become apparent until after a lapse of years

Carcinogenicity

Another long term effect that must be considered is that of carcinogenicity Few cases in which surgical implants have given rise to cancer seem to have been recorded although McDougall (1956) recorded a case in which a sarcoma appeared to have been caused by a plate and screws of dissimilar steels when used to repair a fracture 30 years previously Experimental work in animals however suggests that under certain conditions most of the metals used in surgery can be carcinogenic. Thus Oppenheimer and his colleagues (1956) have caused sarcomas in rats by imbedding tantalum Vitallium and stainless steel foil while Nothdurft (1955) obtained similar results with gold silver and platinum It is noteworthy that the usual constituents of the alloys in common surgical use have themselves been shown to be carcinogenic. Thus Schinz and Uehlinger (1942) produced tumours with chromium Heath (1954) with cobalt and Hueper (1952) with nickel In spite of these laboratory findings there is as yet insufficient evidence to suggest that the use of any particular metal entails a definite carcinogenic risk

Mechanical properties

The mechanical properties required for a metal will depend on the form in which it is to be used and the purpose for which it is intended A foil must be soft and pliable, a plate must be hard and rigid a wire needs considerable tensile strength Tendency to snap under stress and liability to fatigue are also points to be considered In this connexion Key (1941) has shown that although there is little to choose between Vitallium and 18/8/Mo steel from the point of view of inertness the latter is definitely superior in its ability to withstand shock and vibration

Another property to be considered is the ease with which the metal can be worked Vitallium (Vinertia) for example, is difficult to machine and special tools are needed Most of the stainless steels can be bent or machined with ease This point is of importance if it is necessary to modify an appliance in an orthopaedic workshop but attention must be paid to the warning given in the next section about the treatment of metals

The physical properties of a number of metals are given in tabular form on pages 4 and 5 These tables should also serve to emphasize the fact that the words "stainless steel" by themselves mean practically nothing If steel is the metal of choice the surgeon should insist on a steel containing some 18 parts of chromium 8 parts of nickel and 2–3 parts of molybdenum with mechanical properties suited to the task in hand

As the price and availability of metals are governed by unpredictable economic and industrial factors, a discussion of these aspects hardly lies within the scope of this chapter

THE METALLURGICAL PROBLEMS IN SURGERY

III. TREATMENT OF METALS

F P BOWDEN AND J B P WILLIAMSON

In the previous sections of this chapter it has been pointed out that human body fluids are electrolytes and therefore exert a corrosive action on metals immersed in them It has been shown that extremely careful selection of the metals used in surgery is essential if the undesirable consequences of corrosion are to be avoided In almost all cases however the corrosion resistance of a metal depends on its surroundings and on the treatment it has received. It is clear therefore, that it is not sufficient to *select* the right metal it is necessary also to *use* it in a manner which will preserve its passivity This section gives a brief account of some of the physical phenomena which are relevant to the handling and treatment of metals in orthopaedic surgery

It has been pointed out that if two dissimilar metals are immersed in an electrolyte so as to form a cell corrosion will occur very much more rapidly than if either metal had been present alone The surgical importance of this phenomenon was demonstrated by Venable Stuck and Beach in 1937 and discussions of the dangers accompanying the insertion of "mixed metals" have been published periodically throughout the last two decades (*see* for example Venable and Stuck, 1947) Although this work is well known to many surgeons the recent paper by Cater and Hicks (1956) has revealed that in many hospitals little attention has been paid to this aspect of surgery Until the basic principles put forward by Venable and Stuck twenty years ago are clearly understood and accepted (and if necessary protected by an official standardization of the materials used for implants) *there is little point in taking precautions to avoid the secondary causes of corrosion* and the possible tissue reactions which can result from them It cannot be emphasized too strongly that the first step in overcoming the problem of metallic corrosion in surgery must be the use of a single passive metal only

However it would be dangerous to believe that such a standardization will provide a solution for all the problems created by the use of metals in orthopaedic surgery The insertion of "mixed metals" is by far the most important cause of corrosion, but it is by no means the only one There is clear evidence that even in those hospitals where the precaution of using a single passivated metal is routine, tissue reaction is occasionally observed in the region surrounding the implant

Recently the occurrence of very mild corrosion in cases where there is no obvious deterioration of the implant has been studied by Bowden, Williamson and Laing (1955) Samples of the tissues surrounding buried metal were obtained during operations for the removal of internal fixation appliances which had fulfilled their purpose. Great care was taken not to include any samples from cases in which the metal showed any sign whatsoever of corrosion or tarnish. Cases with complications such as sepsis or Paget's disease were also rejected Microtome sections were made of these samples and some were prepared with haemotoxylin and eosin to show cellular detail while others were treated to demonstrate iron infiltration by the Prussian blue reaction

It was found that many of the samples contained unusually high concentrations of iron even though the buried metal showed no evidence of having been attacked by the body fluids A close correlation was observed between the level of iron in the tissues and the degree of cellular reaction which occurred. Heavy iron infiltration

was always accompanied by severe tissue reaction while no reaction was observed in tissues which showed no abnormal concentration of iron The survey also showed that the behaviour varied considerably from place to place over the surface of the same implant It was found that severe cellular reaction occurred in those tissues near the parts of the metal surface which had been handled by surgical tools when the appliance had been inserted This was in marked contrast to the almost complete absence of reaction in the tissues adjacent to those parts of the plates and nails which had not been in contact with tools

Even when the buried metals are chosen so that no visible corrosion occurs it is still possible for them to dissolve into the body fluids to an extent sufficient to cause an adverse reaction in the surrounding tissues It is, therefore very important that the surgeon should give due attention to the causes of this mild corrosion and that it should if possible be avoided until the influence it has on the physiological processes occurring in the healing tissues is more completely understood Some of the factors which can influence the corrosion resistance of metal buried in the body cannot readily be controlled by the surgeon but several result from the manner in which the implants are stored and handled and their effects could easily be avoided.

Damage and metal transfer from tools

It has been pointed out in Section I of this chapter that stainless steels derive their passivity from the impervious coating of oxide which protects them from the surrounding liquid Under normal circumstances this barrier is self sealing But if it is damaged extensively the sealing process may not be sufficiently rapid to re form the protective film The chemical attack would then continue and bulk corrosion would occur It is clear therefore, that great care should be taken at all times to avoid damage to the surface of surgical implants This precaution is especially important during the preliminary sterilization and when the appliances are being inserted Mechanical processes which damage the oxide layer will probably also cause deformation of the underlying metal This in itself may promote corrosion Evans (1946) has shown that the electrode potential in the deformed region can differ from that of the unworked metal Differences in potential of this type ought if possible to be avoided and in particular the practice of bending plates to fit bones ought to be reconsidered with this in mind

Recent investigations have shown that the tools used during an orthopaedic operation can also affect the behaviour of the buried metal. Experiments using radioactive tracers have demonstrated that whenever two metals are brought into contact and then separated, small particles of one are plucked out and remain adhering to the surface of the other It is almost impossible to touch two metals together without causing some transfer of this kind These fragments of metal are very firmly attached to the other surface there is evidence that with most metals they penetrate the oxide layer and adhere to the underlying metal In general the harder metal receives more contamination than the softer but experiments have shown that even when the difference in hardness is as much as twenty times, some fragments of the hard metal can become transferred to the softer surface A general account of the behaviour of metals in contact has been given by Bowden and Tabor (1950)

In a recent study several of the mechanical procedures common in orthopaedic

surgery were performed under conditions as close as possible to those of an actual operation using surgical tools which had previously been made radioactive. The amount of metal which was plucked out from the tool and became adherent to the screws bolts, or plates was measured by counting the radiation emitted from the transferred fragments It was found that in every procedure studied many micrograms of the tool became welded to the appliance The amount of transfer increased markedly if any slip occurred and was in general larger in those operations in which great force was applied by the tool. For example the transfer to a screw ranged from 20 to 40 micrograms, depending on the degree of slip which was permitted between the screwdriver and the screwhead while that from a box spanner to a bolt was between 40 micrograms and 0 1 milligram

It is usual to prepare pilot holes in the bone to receive the screws which secure an orthopaedic plate. A countersunk hole already exists in the plate, since this is prepared during its manufacture. Both engineers twist-drills and special stainless steel ones are commonly used for drilling the bone Frequently these holes are drilled after a plate has already been fixed in place by two or more screws the remaining holes of the plate are used to guide the twist-drill Owing to the convex and wet surface of the bone it sometimes happens that the twist-drill comes into contact with the edges of the plate hole and considerable friction may occur between them Often it is desirable to insert a screw obliquely into the bone if the pilot hole in the bone is drilled through a plate-hole the resulting friction may be severe. Experiments show that when a plate hole is ground away in this manner by a twist-drill the amount of transferred metal can rise to several milligrams

Although the amount of contamination which becomes attached to the surgical implant and is buried with it in the body is very small it may nevertheless exert an important influence on the subsequent behaviour of the passive metal. The foreign metal can provide a second electrode and thus create an electric cell The dissolution of the particle (if it is anodic) will leave a large pore in the protective oxide layer Microscopic examination of fragments of transferred metal indicates that they can be several thousandths of an inch across. Pores of this size in the oxide layer would not readily be sealed by the insoluble corrosion products Thus the dissolution of the tiny particles of foreign metal may lead to the onset of a continuing corrosion of the implant. If the adherent fragments are cathodic continuing corrosion may again result.

Whenever the protective layer surrounding stainless steel is impaired, whether by mechanical deformation or by the dissolution of an embedded foreign particle, the probability that bulk corrosion will be established before the damage can be repaired depends on the supply of oxygen to the damaged surface In general, if little oxygen is available the precipitation process will be retarded and continuing corrosion is more probable. A low oxygen potential can result from the physiological changes occurring in the tissues surrounding the implant during the healing process, or can be caused simply by the geometry of the appliances For example, the surface of the countersunk around the holes in a plate has a very poor oxygen supply when a screw head has been driven down on to it. This increases the possibility that damage done to the plate when the pilot holes are being drilled for the screws will lead to serious corrosion also it emphasizes the importance of the large amounts of foreign metal which can be transferred to the plate during the drilling process

DISCUSSION

The amount of metallic transfer depends on the specific nature of the c tacting surfaces. There are several ways in which its control may be attemp Experiments show that if the tools used are very much harder than the applia the amount of transfer is reduced It is possible however that the mechar deformation caused by the tool will be greater Further experiments are neces to determine the relative importance of these two factors Metallic transfer co be reduced appreciably if a suitable inert lubricant were used between the t and the orthopaedic components This might provide a simple solution to problem and could be especially effective in reducing transfer if used conjunction with non slip screwdrivers This approach is worthy of cl investigation

The use of tools made of metal identical to that of the appliance is an interes possibility The amount of metal transferred would probably be greater t from conventional tools, but the difference in the electrode potential betw bulk metal and the transferred fragments would be greatly reduced

Analytical evidence of corrosion

Biopsy samples of flesh surrounding metal implants have been analysed spec scopically and the concentration of metal ions found was compared with normally present in human tissues. All the samples were taken from reg adjacent to metal which had been buried in the body for 3–4 months Two pi of tissue were taken from the same patient one from near a screw head and other from the surface of an unhandled part of the plate. The concentration chromium nickel, and manganese were very much greater near the metal w had been handled with tools it was six times normal for manganese tw times for nickel and over thirty times normal for chromium No other elem were observed to be present in abnormal concentrations The correspon concentrations near the unhandled part of the plate although high, were significantly outside the normal range The analysis of a sample of tissue adja to a Vitallium screw head revealed over twenty times the normal concentratio both cobalt and chromium the two main constituents of Vitallium These re are typical

There is a close correlation between the region of maximum concentratio metal in the tissues and the site of transferred particles, but there is also evidence that the corrosion is not restricted to the foreign fragments alone high concentration of cobalt observed surrounding the heads of Vitallium sc could not be caused by the corrosion of transferred steel particles but must be to the dissolution of the Vitallium itself

DISCUSSION

The physiological behaviour of the body during trauma and the subseq healing processes create the environment within which the metal implant fulfil its purpose The pH value and the redox potential will vary with time also from place to place on the surface of the metal These variations ca readily be controlled but their effect could be minimized by the careful selec of the particular metal best suited to withstand these electrochemical conditi The use of two different metals in a region with such a complex electrochen

nature is an invitation to disaster Most metal implants are subjected to mechanical stress when fixed in the body in many cases fretting between different components of the appliance may also occur Both these phenomena can influence the corrosion of metal and they too should be borne in mind when selecting the most suitable metal for use in orthopaedic surgery

It is important however that the problem of selecting the metal should not obscure the complementary aspect that of the proper care and use of the appliances Any treatment which increases the chance of a breakdown in the passivity of the metal ought to be avoided whenever possible Care ought to be taken to ensure that the protective surface layer is not damaged unnecessarily at any time, and especially during the operation. The importance of the correct choice of tools ought also to be appreciated There is evidence that fragments of the metal of the tools become buried with the appliance in the body and it is clear that these fragments can initiate a reaction which can result in the corrosion of the buried metal. Analytical evidence supports this view the concentration of metal ions in the tissues surrounding parts of the implant which have to be handled by tools is many times higher than normal even when there is no visible sign of corrosion or tarnishing, while the tissues adjacent to unhandled parts of the same appliance are normal.

In general the mild corrosion caused by the factors discussed in this chapter would not damage the appliance seriously but it can be sufficient to cause a reaction in the surrounding tissues. It ought, therefore to receive due attention and if possible to be avoided until the effect it has on the healing processes is more fully understood

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CHAPTER 2

THE USE OF METAL IN SURGERY

PATRICK G LAING

SINCE EARLY HISTORY when the Bronze Age succeeded the Stone Age and man exchanged his flint knife for one of bronze the surgeon has been to a large extent dependent on the metallurgist for the tools of his craft

This is no less true today as new metals and alloys are developed and presented for our approval and use by the manufacturers in what has been called the Steel Age. To assess the relative advantages and disadvantages of the available products requires considerable knowledge of the recent advances in the study of the corrosion and strength of metals, let alone the engineering principles governing the design and strength of the finished article

In discussing the use of metal in surgery three main applications must be considered The first and undoubtedly the earliest of these uses was to make the knives and instruments used by the surgeon during the operation Secondly we have their use for the construction of irons braces, and splints for the injured and deformed. Thirdly there is the use of metals for the construction of internal splints and implants to be buried in the living tissues of the body

The first and second of these uses will be dealt with quite briefly except in so far as instruments affect the performance of the buried metal implants Metal implants themselves, however will be considered in some detail in an effort to arrive at an understanding of their uses and misuses As the physician must know the chemistry the available forms, the actions of and the reactions to a new drug before giving it to his patients so must the surgeon know all about the metal he proposes to bury in his patients.

AVAILABLE METALS

The rapidly developing science of metallurgy is continually presenting surgeons with new and apparently better metals whose values they must be able, at least partially to assess With a background of the fundamentals of the various types of steels and alloys and of each one s own peculiarities will come sounder judgment in dealing with the claims of various products.

The steels

Steel is essentially a solution of a small amount of carbon in a base of iron, and as such has been known since the days of Aristotle This carbon greatly increases the hardness and usefulness of iron It is only however since the development of the Bessemer and open hearth processes of making steel in the last century that it has become readily available at a reasonable price The addition of other alloying elements into the steel has greatly increased its performance. The most important of these elements are chromium and nickel, and the addition of one or both of these to the alloy produces the stainless steels (*see* Table on p 14)

TABLE

TYPICAL ANALYSES OF ALLOYS USED IN SURGERY

	Tools				*Implants*		
	Martensitic stainless steel	*U.S. tool steel non-stainless*	*A.I.S.I. 420*	*A.I.S.I. 410*	*U.S. Haynes stellite*	*U.S. 316 A.I.S.I.*	*Vitallium*
B.S. Specification No	EN 56C	—	EN 56D	EN 56A	—	EN 58H	—
Carbon	0·19	0·5	0·3	0·15	0·05–0·15	0·08	Trace
Chromium	13·6	—	12–14	11·5–13·5	19–21	17–20	30
Nickel	0·34	—	—	—	9–11	10–14	—
Manganese	0·2	0·4	0·47	1·0	1–2	2	Trace
Silicon	0·24	1·0	1·0	1·0	1·0	0·75	Trace
Molybdenum	—	0·5	—	—	—	1·75–2·5	3
Phosphorus	—	—	0·04	—	0·04	0·03	—
Sulphur	—	—	0·03	—	0·03	0·03	—
Cobalt	—	—	—	—	46–53	—	65
Tungsten	—	—	—	—	11–16	—	—
Iron	Residue	Residue	Residue	Residue	3 max.	Residue	1 max.

NOTE.—The figures give the percentage contents of the various alloys. A.I.S.I. stands for American Iron and Steel Institute specifications.

Certain other alloying elements are used to increase the strength and inertness of the steel. Molybdenum is one of the most important of these from the surgeon's point of view, but small amounts of manganese, vanadium, titanium and other rare metals are all used at times.

The enormous advantages of the iron-chromium-nickel-molybdenum and the chromium-cobalt-molybdenum alloys for the manufacture of metal implants has led to their displacing the vanadium steels used by Sherman (1912).

Stainless steel

The development of the stainless steels, patented in 1913 by Harry Brearley has transformed the face of the world, and it is with this form of steel that we are mainly concerned. Basically a stainless steel is one rendered corrosion resistant by the addition of chromium, or chromium and nickel, to the iron and carbon base. The proportions of these and the addition of other metals varies from type to type of steel with the requirements of the user.

Though there are some 30 commonly used stainless steels, the actual number of

alloys is almost limitless. Slight variations in the method of manufacture, in the number of alloying elements used and in their proportions may completely change the properties of the resulting product The term stainless steel is insufficiently precise for surgical purposes

There are two main types of stainless steel with widely differing properties that concern surgeons

(1) *Martensitic steels* Composed of iron chromium and some carbon They have admirable physical properties but little corrosion resistance It is worth noting that these steels are attracted by magnets whereas the next group are not This provides a rough and ready means of distinguishing the two groups and may be used in checking stock in the theatre cupboard as well as for detecting change from one group to the other induced by insults to the metal

(2) *Austenitic stainless steels* These steels contain about 18 per cent chromium and 8 per cent nickel and combine excellent corrosion resistance with great toughness Other elements such as molybdenum can raise their corrosion resistance in certain media

As far as the surgeon is concerned the latter is the most important class of steels within which there are a large number of proprietary steels

The particular steels most commonly used for the manufacture of implants contain 18 per cent chromium 8–10 per cent nickel and 2–4 per cent molybdenum These steels are covered by the American Iron and Steel Institute (A I S I) specification numbers 316 and 317 and by the British Standard 970—EN 58H and EN 58J for the lower and higher molybdenum values respectively

All these steels fall in the austenitic range and are prepared with a fine grain structure

It is usually recommended that implants prepared from these steels should be annealed to a hardness of 30–35 on the Rockwell C scale, but many are made softer than this and the hardness may vary from part to part of the same appliance

It is probable that the hardness of a metal is related to its physical properties, especially its strength. Apparently two pieces of the same alloy which have been annealed to differing hardnesses when placed together in the body behave like dissimilar metals and set up corrosion at the points of contact.

Implants made of these steels are usually turned forged or stamped from stock bars or sheets obtained from the steel mills, and are then electrolytically polished by reverse plating, to remove all surface debris. After this they are often placed in a bath of nitric acid which, being a powerful oxidizing agent, is thought to perfect and increase the protective surface layer of oxide on the metal, this being known as " passivation

Non-ferrous alloys

The only important example of this type of metal in common use is Vitallium though other such alloys, for example Vinertia and Zimalloy are entering the field. Vitallium is an alloy of cobalt, chromium and molybdenum and implants are prepared by casting in batches. Vitallium has come to occupy a very special place in the field of metal implants due to its great inertness in the tissues combined with excellent mechanical strength Improved methods of manufacture and inspection have to a large extent eliminated earlier inconsistencies in the size of screw threads and so on As a cast metal it has a fairly large grain structure but

its high corrosion resistance and stable grain boundaries appear to make this insignificant. Since Venable's enthusiastic championing of this alloy in the 1930s and 1940s it has attained wide popularity in many fields of surgery

Its hardness averages Rockwell C 28 to 30 and although it develops quite large crystals at the site of a deformity it seems to remain inert over a wide range of circumstances. However it has been shown that the elements contained in Vitallium can be found in the tissues surrounding an implant and some corrosion would appear to be taking place Having said this, it must be reiterated that Vitallium is extremely inert under normal circumstances and a very close approach to the ideal metal

Recently it has proved possible to work a Vitallium (Haynes 25) and instruments made of this alloy have appeared on the market This may have an important bearing on the reduction of what little reaction there is around implants of this metal, by reducing the damage done to them during their insertion.

Titanium

The possibility that titanium steels or titanium itself might prove useful for the making of metal implants was mentioned by Venable and Stuck (1948) Recently it has proved possible to produce almost pure (commercially pure) titanium at an economic cost. The necessity to exclude nitrogen, and therefore air from the melt by the use of a vacuum process has until recently made the cost of implants of titanium prohibitive. Once manufactured, however it appears that the metal can be worked, for instance in a screw turning machine, without loss of its remarkable resistance to corrosion

Experience to date suggests that the inertness of titanium in the tissues provides a metal rivalling Vitallium for first consideration. However titanium is still undergoing experimentation, and although its physical and mechanical properties seem to be most encouraging, its possible defects are not fully determined.

Tantalum

For some time tantalum has been included in most lists of favourites for the ideal metal and it has been included in many experiments. It is widely used for the making of wire sutures instead of stainless steel, and also for skull plates. These uses bring out its great malleability and the ease with which, for instance, skull plates can be cut to size on the operating table using only a pair of scissors.

There is, however a quite marked tissue reaction to this element as has been shown by several workers. This fact combined with its expense and poor availability have temporarily at any rate, displaced it from the manufacture of screws, plates and similar apparatus.

Zirconium

Zirconium which is quite a plentiful element, has excellent corrosion resistance and good physical properties in the commercially pure state, has been used for the manufacture of implants Until recently however it has been in poor supply and rather expensive. It has now been found that this metal is very difficult to render radioactive and therefore it could be widely used in the field of atomic reactors and other similar projects. This has led to the discovery of cheaper and quicker ways of extracting zirconium from its plentiful ores. With the availability

of larger quantities of reasonably priced commercially pure zirconium a reinvestigation of its place in the making of metal implants may have to be undertaken

SURGICAL INSTRUMENTS

The type of metal used for the manufacture of a surgical instrument is to a large extent determined by the job the instrument is expected to perform Light alloys containing magnesium aluminium and so on are often used for the handles of instruments, while a harder more durable steel is usually used at the operative end.

The harder tool steels and some from the poorly corrosion resistant steels are used but the stainless steels are the more satisfactory owing to their being to all intents and purposes rustproof Other steels have to be electroplated and this plating chips off after a little rough handling and the underlying metal corrodes Stainless steels take a rather poor edge and their use for the making of knives is not too satisfactory The development of the discardable blade has solved this problem by removing the necessity for long-lasting edges

Tungsten steels are very hard and a substance called tungsten carbide is second in hardness only to diamond This latter substance is available with a binder of nickel and makes very durable edges for tools Naturally this extreme hardness may cause more damage to the implant in the way of deformation of its surface than would the softer steels and alloys At the moment it is mainly used for cutting tools.

Surgical instruments are now being made of Vitallium and these may prove to be the ideal tools for handling Vitallium implants, both from the point of reducing metal transfer and also by causing less deformation.

Drills and saw blades may be made of either hard and rather brittle tool steels or of stainless steel which is more resilient and less liable to break if accidentally bent during drilling. It appears that metal transfer from drills rapidly declines after the first few operations so advantage may be taken of the properties of the more springy stainless steel drills. It must be emphasized however that fragments of stainless steel instruments that break off during the operation should be removed if this is at all possible If left they may cause trouble by starting a reaction with an "inert" metal implant

BRACES

The development of light but exceedingly strong alloys for the aircraft industry has yielded a dividend to the wearers of braces and artificial limbs By using these various metals, which are often alloys of aluminium or magnesium, it has been possible to reduce the weight of braces and prostheses to a remarkable degree without losing anything in the way of strength or durability The resulting products are not only more aesthetically pleasing but have been an enormous aid to people with weakened muscles who could not manipulate the older heavy "irons"

Combined with this advance in materials has gone a recognition of the import

ance of applying correct engineering principles to the design of the brace or artificial limb to give movements around the correct axis and in the right planes.

METAL IMPLANTS

The use of metallic implants for various reasons is now fully established in surgery and many metals and alloys have been buried in the body at one time or another Venable and Stuck (1948) have covered the early history of the failures of metal to stand up to the corrosive environment of the tissues They showed how of all the available metals, only 18/8/Mo stainless steel and Vitallium could be said to be both inert enough and strong enough to make into plates nails screws protheses and other forms of implants.

In general implants are used to splint healing parts, that is fractured bones, to guide the subsequent shaping of repaired parts such as moulds in joints and cannulas in vessels and ducts, and lastly to replace outworn or broken bony parts

The use of wire sutures for repairing tendons and in some cases for all layers of a wound, and the use of metal plates to repair skull defects, form special cases where malleability may be more important than strength.

The only specifications governing the manufacture of metal implants today are still those of the 1945 report of the Fracture Committee of the American College of Surgeons and are largely the work of Venable, Murray and Fink This group of workers examined 18/8/Mo and 19/9 passivated stainless steels and Vitallium from the points of view both of their inertness and of their physical characteristics *They came to the conclusion that 18/8/Mo and Vitallium were suitable for the* manufacture of metal implants, and as a result both these metals have been adopted and extensively used

An understanding of the advantages and disadvantages of metal implants is imperative to their proper use. The best designed and most inert implant must fail if used in the absence of sound thinking based on established physiological and surgical principles In particular the modern trend is away from mechanistic thinking and towards an appreciation of the fact that bone is a living tissue and a very labile one at that, forming a readily available store of many elements No metal be it ideally inert or not, can resist fatigue by continuously replacing itself as bone apparently does, neither can it " meld " with bone to form a continuous structure The two must always remain just what they are, bone a labile living tissue and metal a dead support or mould

The response of the body to a metal implant

The beautiful piece of cabinet making by the surgeon at the operating table no longer deludes us into thinking that the patient's problems are solved. Tightly inserted screws are soon loosened as the bone melts away under pressure. In fact it is probably true that only dead avascular bone will hold an implant firmly during the first two or three weeks after insertion for this dead bone cannot resorb Later when the fractured bone has united, the implant may lie in a still environment and then, if it is sufficiently inert bone may grow in close proximity to it and hold it so tightly that removal may be a problem

Metallic substitution prostheses, on the other hand, can never lie in a still

environment Constant movements will be taking place in the reconstructed thus rocking the implant in its bed Increasing complexity of geometric des the stems of these prostheses in an effort to hold the bone more firmly cann expected to solve this problem Bone will always give way where it is presse this is a fundamental obstacle to the use of implants of any substance

An implant may hold bone ends in apposition while they unite it may gui shape of the healing tissues in an arthroplasty it may keep open a vascu biliary channel and guide the reforming intima and adventitia but if the ope is to be of lasting benefit, living tissues must take over from the dead im Only in the aged and the fatally ill is it reasonable to use prosthetic implar purely mechanical reasons when for instance one wants to mobilize the p without waiting for healing of the fracture

The influence of the healing process on metal implants

A metallic implant in the tissues is exposed to the changing environmer accompanies the healing of the wound At first it is surrounded by fresh then by the blood clot next by granulation tissue and finally either by scar or by osteoid and new bone, depending on the circumstances

Fresh blood has a high oxygen tension and a *p*H of about 7·4 for a short At once a clot forms and oxygen is lost and carbon dioxide accumulated le to a fall in the *p*H which may reach 5 These changes are accentuated if cl either does not take place or is succeeded by liquefaction in the absence of e zation Usually this stage soon ends and the *p*H slowly returns to normal ov course of a few days. Infection of the wound may prolong the period of th tide or in the case of some bacteria may produce an alkaline tide which wi pass off with the end of the infection

The acid tide is a factor which may accentuate the action of any cen corrosion already operating on the metal surface thus making the effect of more severe and more widespread

The natural history of the healing of a fracture in a vascular bone applie to the bone traumatized during the insertion of a nail or screw

The loosening of the implant that takes place in the second and third following the operation is due to the local vascularity and resorption of bor is seen at any bone end This process is succeeded by the reformation of b close contact with the metal The more inert the metal the tighter will it be gr providing it is not rocked in its bed Rocking of the implant for whatever will cause further bone absorption and loosening.

The inertness of metal implants

This subject is considered in detail in Chapter 1

The ideal metal for implantation

It may be useful to consider the properties of the ideal metal for implar into the tissues. This metal must be completely inert in the ever changing er ment of the tissues and must be able to maintain its corrosion resistance presence of varying *p*H values changing oxygen tensions at various points surface and constant movement of the parts about it. It must be capable of produced with a more or less constant composition from one batch to anot

FIG. 1.—Section of tissue adjacent to an unhandled implant of Vitallium. A few flattened cells line the metal-tissue interface. No reaction can be seen in the surrounding and no iron salts were demonstrated. (× 75.)

FIG. 2.—Section of tissue adjacent to an implant of type A.I.S.I. 316 stainless steel. Reaction is more marked than in Fig. 1, with a more distinct lining membrane, and some fibrosis is present. No iron salts are seen. (× 75.)

FIG. 3.—Tissue that had been in contact with a handled A.I.S.I. 316 screw head. Iron salts are seen streaming away from the metal-tissue interface and are giving the Prussian blue reaction. Dense fibrous tissue and numbers [illegible] pale histiocytic cells are seen. (× 95.)

FIG. 4.—Tissue that had been lying in an A.I.S.I. 316 screw slot. Dense deposits of iron salts are seen and the whole is vascular and shows a typical "electrolytic inflammatory reaction." (× 75.)

FIG. 5.—This tissue had been in contact with an A.I.S.I. 316 bolt head that had been heavily handled. Iron salts show as black deposits in the highly vascular scar tissue. (× 75)

FIG. 6.—Iron salts, demonstrated by the Prussian blue reaction, shown in the cytoplasm of large histiocytes. Quite large particles can be clearly seen. (× 625)

that one may safely mix screws bought at different times without fear of introducing "mixed metals" and thus causing corrosion.

The strength of the metal must be such that it can bear any reasonable strains thrown on it while performing its task without breaking or bending. Even with the use of adequate external splinting the implant may have to take breaking stresses for many months, for instance in a fracture of the femoral neck with an avascular head.

The metal must be in good supply and reasonably inexpensive. It must be easily worked or cast without developing faults or cracks.

There can be little doubt that Vitallium comes nearest to our conception of the ideal metal. Some solution of this alloy does, however occur in the body as has been shown spectroscopically

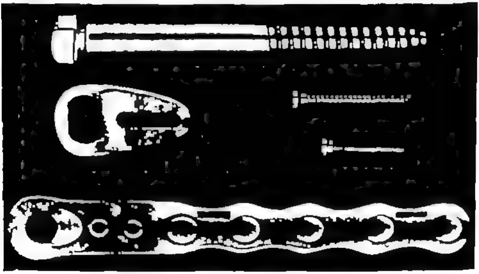
At the moment titanium, which, unlike the chrome-cobalt-nickel alloys, can be easily machined, is making a strong bid for favourite place, being inert, light and tough.

Internal fixation of fractures

The points already made can best be underlined by a consideration of surgical materials in the internal fixation of fractures. The development of the new steels and alloys for the manufacture of the implants used in this branch of surgery has been well covered by Venable and Stuck (1947)

The last ten years has seen a growing awareness of the real causes of failure of

(a)



(b)

FIG 8.—(a) Radiograph of patient's hip containing an intertrochanteric appliance. The fracture has united but the screw and plate are surrounded by a granulation-filled space. The surrounding bone is slightly sclerosed. (b) The metal parts from the same case. Danger mixed metals! The central screw was made by another manufacturer and, though in the range A.I.S.I. 316, it had a slightly different composition from the rest of the metal. The whole proceeded to corrode, as can be clearly seen. It is worth noting that the corroded screw is highly polished while the areas of the plates which have been attacked are discoloured.

material will absolutely prevent these unwarranted stresses bending or breaking the implant.

However certain factors are being attended to with benefit Welded junctions between metal parts are being eliminated in favour of the making of each appliance out of one piece of metal by forging or casting

The use of coarse threaded screws which take a deeper bite of the bone is practically universal Even with some circumferential absorption of bone these screws do not tear loose as easily as do the fine threaded ones.

The modern accentuation of the importance of shortening of bone during the early stages of fracture healing is reflected in the popularity of slotted plates such as Eggers plates, and of various nails. Both types of implants allow muscle pull to

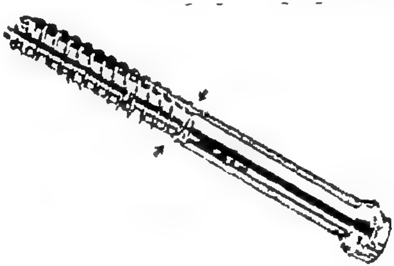


FIG 9—A Lorenz screw which fractured at the spot marked by arrows The femoral head was avascular and delayed union resulted. The patient took weight on the leg and so overstressed the metal. Stress cracking resulted and the implant fractured. (*By courtesy of Crucible Steel Research Department*)

maintain bone end apposition in spite of bone absorption at the fracture site. This principle of allowing shortening in shaft fractures is by no means universally accepted yet, for some surgeons regard the bone end radiolucency as an indication that normal healing processes are operative It cannot be denied that true distraction is very dangerous There is a tendency to feel that true external splintage is more important to fracture healing than the use of "sliding" implants Blade plates for fractured necks of femur are now designed to allow shortening of the neck to take place without forcing the nail into the hip

In general however there is a tendency to use stronger plates than those designed by Sherman (1912) and buttressing along the sides of the plates and absence of narrowing between the screw holes can be indulged in with really inert metals for the total mass of buried metal is less important from a corrosion standpoint than it was earlier in the century

Intramedullary nails are widely used nowadays and solid rods and complex

"clover leaf" patterns vie for popularity. Bending stresses on these nails are tremendous unless the limb is adequately splinted following the operation and no design can eliminate the danger of bending or breakage.

The use of cross slotted and Philips headed screws with screw-holding screw drivers is a great help in eliminating tool implant slipping and thus helps to eliminate metal transfer between the two. Stainless steel screws are now made with cross slots and Woodruff slots, while Vitallium Philips headed screws are available.

Care of implants

The care of metal implants at all times from their manufacture up to and including the period they are buried in the body must be governed by the knowledge of their susceptibility to corrosion once damaged, or contaminated by metal transfer. This is especially true in the case of the stainless steels, but also in the case of Vitallium, titanium and other metals. Damaged stainless steel is no longer stainless and should not be buried in the tissues.

No implant is ever used twice in its life, especially if it has once been strained to the bending point. In this latter case it would not even be used again on the same patient for it will have been permanently weakened.

Metal implants are stored separately in their plastic containers until ready to be sterilized. They are not allowed to rattle about in a cupboard drawer to become scratched and contaminated by metal transfer from the drawer and other implants. During sterilization each implant is protected from damage by being wrapped in gauze or another soft material. Storage on metal screw and plate racks may be dangerous for the implants become scratched and pick up metal from the rack, leading to loss of their inertness. If racks are to be used they should preferably be made of plastic.

Each company's products are kept separate and are never used together for they are usually made from steel differing in composition and are thus incompatible in the tissues.

During the operation the implants are handled with the greatest care to avoid damaging them and are gripped with the minimum of force. Picking up a screw with a haemostat may squash its threads badly unless great care is taken. Drills should never be allowed to grind against plate edges or the plate may corrode later. Not only does this contact damage the plate but considerable metal transfer takes place.

The tools used to handle implants are being designed to lessen damage to metal surfaces and decrease the amount of metal transfer. Experiments are being undertaken to discover the ideal properties of screw-drivers and spanners both for type of steel used and the hardness of the finished product.

Stainless steel wire is made out of many types of such steels and one must make sure that the manufacturer is supplying 18/8/Mo wire. The straining and kinking that wire undergoes during insertion accounts for the corrosion and breakages seen even when the most inert wire is used. Its use with metal plates and screws is probably not wise for this reason since the two may easily corrode. No badly kinked or damaged wire should be buried in the tissues if healing is to be free of avoidable complications.

PRESENT LINES OF ADVANCE

The development of titanium and the newer methods of producing zirconium are all of interest to the surgeon The properties of various strong and corrosion resistant stainless steels are being investigated with a view to finding the ideal metal for implants The production of steels in a vacuum may help to increase their strength and inertness by decreasing the amounts of dissolved gases and so lead to a more inert metal Recently Neutrillium, a stellite alloy with low iron content, has been developed and is being tested It is known to be highly corrosion resistant and very strong.

The metals used for the manufacture of the surgeon s tools are being reinvestigated with a view to reducing the amount of metal transfer to the implants during their insertion without at the same time making the tools too hard and deforming the screws. The avoidance of cold rolling as a method of making screws and other implants will eliminate much of the internal stresses in the finished article A rolled product is squashed and deformed internally so making it highly susceptible to corrosion

Better methods of manufacture with a much tighter specification of the metals used will only follow the surgeon s demands for them. It is probably as much the surgeon s responsibility to know the properties of anything he buries in the body as it is to be aware of the full advantages and disadvantages of the drug he administers

The behaviour of Vitallium remains as near ideal as that of any alloy but there is no reason why 18/8/Mo stainless steel of a strictly controlled analysis and strength should not continue to be used by surgeons who prefer it.

Research into the effects of small quantities of the elements contained in implants on the enzyme systems operating in bone healing is urgently needed before we can understand the meaning of inertness and so-called electrolytic inflammation " Work at present being done on the mechanism of ossification and on the tissue respiration of bone may yield useful results, and help surgeons to make a choice between the various metals available for the manufacture of implants

The need is now for a concerted effort on the part of steel manufacturer instrument maker and surgeon to ensure that metal implants shall be produced within a tight specification as to analysis hardness and method of production. After that it is the surgeon s job to take proper care of the implant before and during its insertion into the tissues and to protect it from undue stress after insertion.

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CHAPTER 3

PATHOLOGICAL EFFECTS FROM SURGICAL METAL

J H Hicks

INTRODUCTION

All metals, even the noble metals, corrode to a greater or lesser extent in certain conditions such as those met with in the tissues. By corrosion is meant that the metal is attacked by the surrounding fluid, forming compounds that may be soluble and chemically active The effects of this upon the tissues depend upon (1) the rate of corrosion and quantity of corrosion products present and (2) the toxicity of these products. The commonest form of corrosion occurs diffusely over the whole surface of the metal article without having any visible effect upon it. With the so-called non-corrodible metals used in surgery the magnitude is about one tenth of a milligram to 1 milligram per square centimetre per year The more familiar pitting corrosion is a form peculiar to the stainless steels (Fig. 10) It is

Fig. 10.—Stainless steel (EMS) screws showing pitting corrosion.

only of occasional occurrence, but when it does start the electrochemical action occurs at a particularly high rate in these pits The quantities involved may be several milligrams as in many months. One must not be misled because this type of corrosion is visible into forgetting that surface corrosion is frequently and perhaps always taking place whether or not pitting corrosion occurs It is convenient to refer to these two forms of corrosion as macrocorrosion and microcorrosion or visible and invisible corrosion (from the effect upon the metal rather than upon the tissues)

PATHOLOGY

The effects upon the tissues are two namely a fibrotic reaction and an inflammatory reaction. These represent fairly clear-cut phases in a graduated series of changes starting from an almost zero reaction. Tables I and II gather together various observations and attempt to correlate tissue reaction with the common metals used in surgery (This information in some instances is very tenuous and must not be accepted as final.)

TABLE I

SUMMARY OF EFFECTS OF METALS USED IN SURGERY

Individual elements	*Toxicity of corrosion products*	*Known effects*
Iron	Moderate	Fibrosis. Siderosis or pigment inflammation.
Chromium	Highly toxic	? cellular death. ? liver necrosis. Local or generalized eczema.
Nickel	Not very toxic	Chemical inflammatory reaction. ? eczema.
Cobalt	*Moderately toxic*	*Lysis of bone.*
Molybdenum	?	?
Manganese	Highly toxic	New bone formation.
Vanadium	Highly toxic	?

TABLE II

Alloys[1]	*Incidence of corrosion*	*Degree of corrosion*	*General effect*
Steel	*High*	*Severe*	*High* incidence of severe or moderately severe inflammatory reaction.
Vanadium steel	High	Severe	As for steel.
Chrome steel	Moderate incidence of pitting corrosion. Moderate incidence of microcorrosion only	Moderately severe	Moderate incidence of severe or moderately severe inflammatory reaction. Small proportion show minimal reaction.
FSL	Small incidence pitting corrosion (? only when mixed with EMS). Microcorrosion *only in the majority of* cases.	Slight	Low incidence of mild or moderate inflammatory reaction. Large proportion show minimal reaction *only*
EMS	Moderate incidence (40 per cent) of pitting corrosion when mixed with FSL. Microcorrosion probably as for FSL.	Moderately severe	Moderate incidence of moderate or severe inflammatory reaction. Moderate proportion show minimal reaction.
18 8 Mo	Very small incidence of pitting and fretting corrosion. Microcorrosion probably as for FSL.	Slight	Very low incidence of mild inflammatory reaction. Nearly all show minimal reaction only
Vitallium	Pitting corrosion unknown.	Nil	Low incidence of mild inflammatory reaction. The remainder show no reaction at all.

[1] The popular although sometimes inexact names will be used throughout. Ambiguity is removed by the definitions given in the Appendix at the end of the chapter

[2] It is possible that these cases are due to metallic transfer from screwdrivers and drills and that if Vitallium appliances could be put in with Vitallium tools there would be no reaction at all.

The fibrotic reaction

This gives no clinical symptoms The fibrosis is seen as an unpigmented layer of tissue up to 1 or 2 millimetres thick covering the metal on every side On the surface it is encountered as a layer smooth shining and non adherent to the metal that has to be turned aside when a plate is being removed In the substance of the bone it lines the nail or screw track forming a complete layer of soft tissue between metal and bone It is the immediate cause for the slight looseness of nail or screw that is found fairly commonly Sometimes this layer of fibrous tissue is reduced almost or quite to zero and the screw lies then in direct contact with the bone and is not loose. This of course is always the case when the bone is dead since no reaction of any kind occurs for months or years but it also occurs quite frequently with normal living bone and in fact a screw may become gripped more tightly than when it was inserted Such a case provided the specimen for Fig. 11 the screw and the bone having to be removed *en bloc* by a trephine

FIG. 11 —Minimal reaction. Section of bone around a (Vitallium) screw Living bone is in direct contact with metal in most places. In a few places a very fine layer of fibrous tissue has developed between bone and metal. (× 16.)

The fact that this can occur in a moderate proportion of cases suggests that zero reaction is the true response to the chemically inert foreign body and that the fibrotic reaction is the response to varying degrees of microcorrosion The fibrotic reaction occurs usually with metal that is showing no visible corrosion and appears only in the peripheral parts well away from the source of corrosion when the metal is undergoing macrocorrosion and this also suggests that fibrosis is the response to the more minor degrees of corrosion.

Characteristic appearances of the fibrotic reaction of moderate degree are shown in Fig. 12 The tissue is a vascular collagenous fibrous tissue.

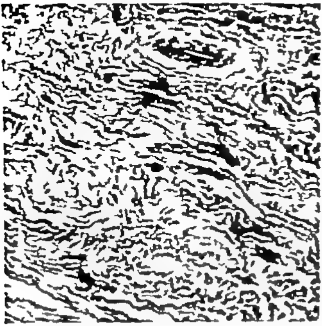


FIG. 12.—The fibrotic reaction. Tissue overlying an 18 8 Mo screw (× 125.)

The inflammatory reaction

The gross inflammatory reaction to be described always accompanies visible corrosion, although mild and intermediate reactions sometimes occur near to metal that is not showing visible corrosion. The clinical, pathological and radiological features are specific. The following original description is based upon a detailed study of over 40 cases arising from screws of the type illustrated above (Fig. 10).

Clinical features

One or two weeks after plating, corrosion may present with all the appearances of a cellulitis The skin becomes red, shiny hot, tender and oedematous. This may subside or may become worse. If it subsides it passes through a subacute stage in which redness warmth and tenderness become localized to the site of the corroding screw This may persist so that many months after the plating the examining hand passed over the limb can detect a patch of warmth in the skin. This, at a site other than the fracture site, is almost diagnostic of a corroding screw even when there are no other signs at all. It must be emphasized that the perfect plating, by contrast, is completely symptomless and sign-free from the second or third day onwards.

If the inflammatory reaction becomes worse the wound next begins to ooze serosanguineous fluid. It then may burst away from the hold of the sutures and gape to reveal profuse wet granulations (Fig. 13), sometimes exposing the under lying bone or plate. This state persists for several weeks. Then the granulations begin to lose their oedematous appearance Epithelium spreads in from the periphery but ceases before covering the whole area, leaving one or two sinuses or button granulations which lead down to the corroding spot on the metal. These resemble the sinuses or button granulations associated with a sequestrum or a non-absorbable suture and, like these, continue to discharge for months or intermittently for years unless the source of the trouble is removed.

FIG. 13.—The breaking down operation wound

Another form in which the corrosion reaction presents is as the so-called "infected haematoma" This is a collection of dark red fluid which forms under the skin and either bursts through or has to be incised like an abscess. Bacteria are not always present.

The most chronic form of the corrosion reaction remains after incomplete subsidence of the acute or subacute forms or may arise *de novo* 20 to 35 weeks after insertion of the metal It is a red induration extending widely around the wound and is later followed by an eczematous scaling of the skin (Fig. 14) This is quite often seen but is mistakenly attributed to the effects of plaster or one of the natural stages in healing of a fracture and its significance is not appreciated

FIG 14—The eczematous reaction.

Macroscopic appearances

Fig. 15 shows the pathological appearances in a moderately severe case The tissues are pigmented and oedematous the periosteum is thickened and strips easily the bone is soft and hyperaemic and there is a region of destruction around the focus of corrosion granulation tissue and necrotic debris surround the metal

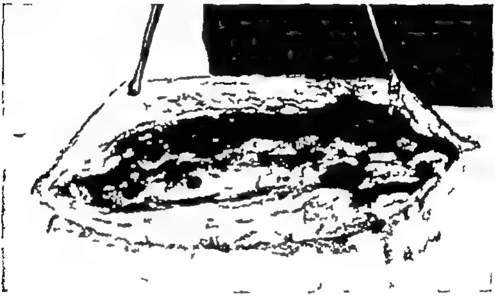


FIG. 15.—Pathological appearances in gross corrosion.

a collection of purulent fluid may be present some or all of the screws, non-corroding in addition to corroding ones, are loose, the screw holes being large and filled with granulation tissue patches of dead bone and occasionally ring sequestra may occur

Microscopical appearances

A dense cellular infiltration extends for several millimetres in the connective tissue around a focus of corrosion Fig. 16 shows the edge of such an area. The majority of the cells are macrophages and there are lesser numbers of small round cells. The macrophages are loaded with pigment granules which on appropriate staining prove to be iron Elsewhere in the section can be found foreign-body giant cells and free deposits of iron and other pigments. There are almost no fibrillar elements in the central zone, but more peripherally fibres become predominant and the appearances become those of the fibrotic reaction already described.

Although this picture must have been seen many times only very few workers have described it and associated it specifically with corrosion. Others have simply called it a severe inflammatory reaction However if it is compared with the inflammation of sepsis (Fig. 17) completely different pictures are found. The cellular infiltration in septic osteitis consists entirely of polymorphonuclear leucocytes and plasma cells It seems that the distinct nature of the cellular reaction in corrosion is not fully recognized

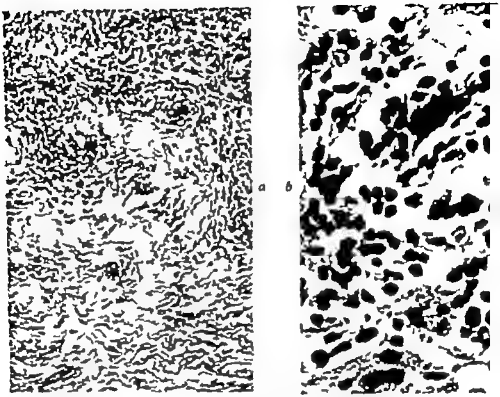
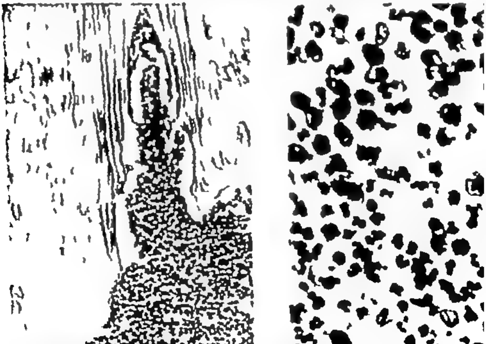


FIG. 16.—The inflammatory corrosion reaction. (*a*) Low power view showing the tra
central cellular zone to peripheral fibrotic zone (× 125). (*b*) High power view o
area (× 600). Macrophages and small round cells predominate. Bacteriologically th



(× 125)

FIG. 17. Septic osteitis showing a cell population distinguishable from the above. I
surrounded and infiltrated by polymorphonuclear leucocytes and plasma c

Bacteriology

If cultures are made on first reopening a corrosion wound only a small proportion reveal pathogenic organisms (and these are present only in small numbers quite distinct from the heavy growth of a septic osteitis) A fairly large proportion reveal non pathogens such as micrococci or diphtheroids. Some show no organisms at all. The important fact that these wounds can on occasion be sterile is easily overlooked because secondary infection is so ubiquitous. The conclusions to be drawn from this are (*a*) that the typical corrosion reaction can and sometimes does occur in the absence of infection, but (*b*) that corrosion does in some way seem to predispose to the persistence of organisms as saprophytes long after they would ordinarily have disappeared.

Radiological signs

In addition to the generalized decalcification which occurs when a fracture is doing badly from any cause whatever the radiological signs in corrosion are (1) *peripheral new bone* at a site other than a fracture site, for example around the head or point of an offending screw (Fig. 18) and (2) *cylindrical rarefaction*, best seen in almost end on views of the screw (Fig. 18*a*) or as an *eroded area* of the cortical bone around the screw hole seen on profile views (Fig. 18*b*) The peripheral new bone, which histologically appears as islands of woven bone free from pigment in the cellular fibrous tissue at some distance from the focus of corrosion, has no connexion with the fracture site and is useless for union The cylindrical rarefaction around a corroding screw represents the region of bone destruction and such a screw is found to be quite loose and surrounded by granulation tissue in a wide hole. These signs are to be seen repeatedly in the published radiographs of animal experiments whenever corrosion is occurring.

(*a*) (*b*)

FIG. 18.—Radiological signs in corrosion. (*a*) Peripheral new bone, cylindrical rarefaction (*b*) Peripheral new bone, erosion. (In (*a*) the actual corrosion pit occurs as a visible defect in the metal.)

Eczema as a complication of corrosion

Both nickel and chromium are known to cause eczema when in contact with the surface of the skin and cobalt is considered to be quite capable of doing so Two of these three metals will be released into the tissues when either stainless steel or Vitallium undergoes corrosion It therefore seems that the localized eczema of skin which is fairly common over a stainless steel plate (Fig 14) and occasionally over a Vitallium plate may be due to the products of corrosion Although eczema is often attributed to the plaster of Paris this cannot be the explanation in the cases in which plaster is not used Two cases are known in which generalized eczema developed In one this occurred after the disturbance caused by the removal of the corroding metal which had until then only caused local eczema In the other it arose about 4 months after a Smith Peterson nailing in a patient who had complained of minor pains and whose radiograph showed cylindrical rarefaction around the nail Patch tests on unaffected skin with pieces of gauze soaked in 5 per cent solutions of a nickel salt and a chromium salt gave a positive result for chromium When the nail was finally removed, although it did not show pitting corrosion it was found to have been manufactured of two different metals molybdenum steel for the head and FSL for the shaft When a generalized eczema is seen some months after an internal fixation the possibility that it may be a symptom of corrosion should therefore be borne in mind and the patch test as used by dermatologists might prove a useful adjunct.

AETIOLOGY OF THE CORROSION REACTION

The argument as to whether the tissue changes are caused by an electric current or by a toxic effect of the metallic salts still continues after 20 years As regards the corrosion of the metal itself physicists leave us in no doubt that this is an electrochemical phenomenon It is impossible for the one to exist without the other or as has sometimes been claimed, for the one to precede the other The argument arises over the question as to which part of this phenomenon, the electrical or the chemical, causes the effects in the tissues Venable and Stuck (1937 1947) have propounded the theory that electrolysis and not toxic action is responsible However one experiment has been misinterpreted. To demonstrate the passage of an electric current between screws of dissimilar metals in a bone they connected them to an ammeter (Fig. 19*a*) and—quite correctly—showed that a current flowed. What they ignored was the fact that in their other experiments—the ones in which they showed corrosion changes around pairs of screws in the bones of dogs—and in clinical practice the metals are *not* connected to an ammeter (Fig. 19*b*) No one denies—and several workers have repeated—the experiment which shows that a current flows when the circuit is completed but the experiments certainly do not prove that a current is flowing when no circuit is completed Of course if the two dissimilar metals are in contact as in Fig. 20 the circuit is completed and the conditions become the same as those set up in the ammeter experiment but the inference that electrolysis is the cause of the tissue reaction whether or not the metals are in contact is

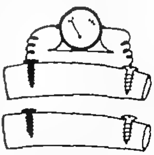


FIG 19—The misinterpreted experiment of Venable and Stuck.

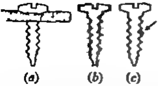


FIG. 20.—Dissimilar metals in electrical contact. Circumstances in which "electrolysis" could occur (a) Screw of one metal in contact with plate of another (b) Screw of one metal plated with another metal. (c) Screw of one metal with a chip or scraping of another metal (perhaps microscopic) or with an exposed fragment of an impurity

incorrect All that can be claimed for electrolysis is that it causes dissimilar metals to undergo focal corrosion more readily and determines the spot where this corrosion will start

Bothe Beaton and Davenport (1940) and Bothe and Davenport (1942), in supporting the toxic chemical theory are on firmer ground. They placed metals in pairs (but not in contact) in the bones of animals and observed that the effect on the bone was specific to the individual metal For instance manganese produced the same severe reaction whether it was paired with Vitallium, titanium or stainless steel or was in isolation, whereas titanium produced no reaction whether in isolation or paired with platinum Vitallium or silver and so on

The chemical toxic theory is supported by the tissue culture experiments of Ménégaux, Moyse and Odiette (1934) and Ménégaux and Odiette (1935) They showed that fragments of copper mild steel and similar metals in a culture of fibroblasts or osteoblasts slowed growth or stopped it altogether Silver tantalum and nickel had a moderately inhibitory effect. Gold and stainless steel had no detectable inhibitory action at all. Since they were using single metals there could be no electric current passing through the tissue but they went further to show that the effect of metals in pairs whether separated or in actual electrical contact was no different from that produced by the individual metals alone. A further useful result from this work is the recognition of three groups of metals, the highly toxic, the slightly toxic and the non-toxic. Campbell, Meirowsky and Hyde (1941) add vanadium to the highly toxic group and Vitallium to the non-toxic group

Clinical experience also lends support to the toxin theory If in an established case of corrosion only the metal is removed and the surrounding pigment-containing tissue is left, healing takes weeks or months If the pathological tissue is excised the wound heals promptly The slow healing in the former case cannot be explained electrically once the metal has been removed, but if the toxin theory be accepted it is easy to explain it as due to the persistence of the products of corrosion. This is one occasion on which differentiation between the electrical and the chemical parts of the corrosion reaction, which might seem to be only of academic interest, is of practical importance.

CORROSION AND SEPSIS

The clinical, pathological and radiological characteristics described do not appear previously to have been attributed specifically to corrosion. This presumably is because they so closely resemble wound infection that no distinction has been made Both conditions can on occasion present as cellulitis, abscesses, discharging wounds and sinuses, while radiologically the peripheral new bone of osteitis differs only in being more widespread The crucial distinction namely that the corrosion reaction can occur in the absence of bacteria, is obscured by secondary infection frequently enough to have been missed. Cretin and Pouyanne (1933) are the only workers to refer explicitly to an aseptic inflammatory reaction due to chemical

irritation The condition whilst being accepted as an inflammation should be considered as one essentially of chemical and not of bacterial origin This is supported by the fact that antibiotics fail to produce any definite improvement whereas removal of the corroding metal and excision of the pathological tissues does Further evidence is provided by the sudden drop in the incidence of wound inflammation that follows the elimination of corrodible metal from the stock of the operating theatre even though the opportunities for wound infection remain as great as before (Cameron 1940 Cater and Hicks, 1956)

Since the physical signs of the two conditions are so similar it seems certain that cases of corrosion have often been misdiagnosed as sepsis This mistake was certainly made in the early stages of an outbreak in the author s experience and it brought the conviction that the two have been and still are being, confused What could be a typical case is illustrated in the Watson Jones textbook, cited as sepsis due to plating a compound fracture The idea of corrosion is so foreign that the diagnosis is not even mentioned and yet at least two different patterns of

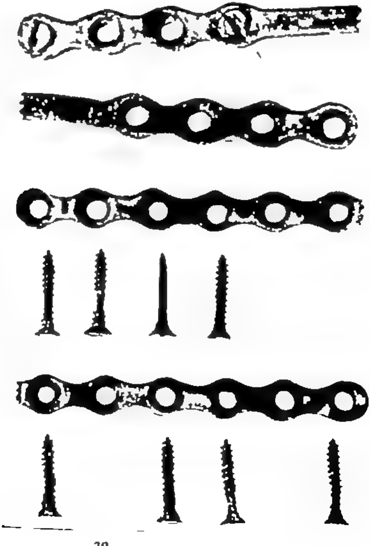


FIG. 21 —Plates, recently removed from the femur dating from before the stainless steel era In a more superficial bone the inflammation caused by this amount of corrosion would probably have been diagnosed as sepsis. (The division of the plates into halves is artificial.)

screws, probably of differing alloys, are visible in the radiograph It is interesting to speculate upon the extent to which current beliefs may have been influenced by confusion of the two conditions Teaching handed down from Lane's day emphasizes the high risk of infection in bone surgery but the metal used then was vanadium steel or some other form of non stainless steel which had a high rate of corrosion (Fig. 21) Corrodible metal has been on the market continuously except for two breaks, one of 9 years and one of 3 years, from that day to this. It seems probable, therefore that it was all the time corrosion misdiagnosed as sepsis, that gave rise to belief in the high susceptibility of bone to infection. Modern experience is that bone is *not* particularly susceptible and it has been discovered once corrosion is excluded, how resistant it is even in theatre conditions that give a high wound contamination rate and in the routine plating of gross compound fractures This is not to be taken as an excuse for relaxation of oligoseptic ritual (since the effects of sepsis when established in bone are so serious), but it is intended *to show that there need be no fear of metal provided it is non-corrodible.*

EFFECT OF CORROSION UPON BONE UNION

The question as to whether the corrosion reaction can have any effect upon the uniting fracture has not been adequately dealt with writers on the subject having seldom progressed beyond observations on local changes These are not very helpful however because recognizable effects die away within 1 centimetre of the focus of corrosion whereas the fracture line is usually at a greater distance than this The occasional production of callus around a corrosion focus (page 36) has been put forward as an advantageous feature likely to promote union, but no one has shown that this callus has in fact any tendency to bridge the fracture line Clinical experience reveals differing effects. Time to union is normal in about half the cases of corrosion In the other half it is prolonged. It seems, therefore that some indirect and sporadic factor is at work.

A probable explanation is suggested by the fact that when corrosion occurs, many of the screws, including non-corroding ones, become loose Screws can of course become loose as a result of purely mechanical irritation For example, a plating that is initially mechanically imperfect can become progressively more imperfect as a result of slight movement, the movement causing irritation and the irritation giving rise to decalcification and further loosening, *whereas a plating* that is initially mechanically perfect tends to stay so If however corrosion occurs, loosening of screws will result from the chemical inflammation. The firm hold of the plate will thus be lost. This is no place to enter into a discussion on the merits of rigid fixation but it can be argued that if the fixation conferred by a plating has any beneficial effect whatsoever on the process of union corrosion will, in some cases cause that advantage to be lost. It is suspected that these are the cases that show a prolonged time to union.

MICROCORROSION

If " micro methods are used, corrosion effects can be detected around metallic implants in 100 per cent of cases. These minimal changes are (1) fibrosis, (2) a few areas where granules of pigment are deposited, (3) a positive Prussian-blue reaction (iron) in the fibrous tissue generally or in local areas and in most of the granules, (4) local collections of round cells limited to perivascular zones, (5) the

persistence of organisms (often non pathogenic) after they would normally have disappeared These effects are found in association with the "safe" metals 18/8/Mo and Vitallium and include the large majority of cases which have progressed perfectly satisfactorily and in which the metal has been removed for other reasons (One peculiar feature is that Vitallium implants are associated with Prussian blue positive pigment. Vitallium contains as an impurity less than 2 per cent of iron and this may indicate that the iron is coming by metallic transfer from the tools used for insertion of the implant Bowden Williamson and Laing, 1955a and b) A small proportion of cases (smaller with Vitallium than with 18/8/Mo) do rise above the threshold of clinical significance and produce signs and symptoms that occasionally necessitate removal of the metal before the wounds will heal properly The only significance otherwise is that modern surgical metals (or perhaps the method of putting them in) are only just satisfactory and that further work is still necessary One promising new metal titanium, is already being tried Meanwhile one can continue to use present metals with the knowledge that they will give no trouble in over 90 per cent of cases

THE FUTURE

Macrocorrosion will soon disappear Nearly every case in the past few years has probably been caused either by chrome steel (used for trifin nails) or by one particular pair of stainless steels in combination—namely EMS screws with FSL plates (Cater and Hicks 1956) Chrome steel nails have not been sold for 15 years and EMS was only used for one pattern of screw (the fine thread Sherman) and in any case went off the market in March, 1954 Thus in those hospitals where all the chrome steel has been used and where screws of the particular pattern were not used corrosion is even now unknown (This explains the sporadic occurrence of the reaction and the fact that some surgeons are unfamiliar with the picture presented in this chapter) In 1956 complete standardization by every manufacturer in England for the type of stainless steel to be used in orthopaedic surgery was reached and it is now impossible to buy anything but 18/8/Mo It follows that theatre stocks are gradually becoming clean either as old metal is used up or as a result of deliberate efforts to eradicate it. As this occurs the problem of corrosion will almost disappear All that will remain will be the misleading effect it has had upon our conception of bone infection

APPENDIX

Nomenclature and History of Surgical Metals

Those mentioned in the text are printed in italic type

Steel includes carbon steel and mild steel. Sometimes plated with cadmium copper nickel or silver Introduced about the beginning of the century and (as silver-plated steel) sold until 1935

Vanadium steel covers a group of steels containing 0 1 to 0 15 per cent vanadium together with small amounts of chromium molybdenum or other elements. They have particular qualities of strength and surface hardness. Introduced to surgery about 1912 and sold until 1935

The above two steels were the only ones available until the introduction of the stainless steels.

Chrome steel covers the group of "martensitic" stainless steels containing 12 per cent to 16 per cent chromium and small quantities of other elements but no significant amount of nickel (British Standard Specifications En.56C, En.56CM En.56D and En.57). Chrome steel (En.56C) was introduced for trifin nails in 1931 * Some plates were also made in chrome steel It continued on the market until about 1941

FSL (B.S Specification En.58E) is one of the group of "austenitic" stainless steels. They contain nickel 8 per cent to 12 per cent in addition to chromium, 18 per cent, hence "18/8" is a name loosely used for any member of the group Other members of the 18/8 group are the steels known as FST (En.58A) and *EMS* (En.58M) FSL and FST were first used for screws and plates respectively in 1936. FST was discontinued in 1941 but FSL has remained on sale almost until the present day † EMS contains a larger amount of manganese and has free-machining properties. It was sold between 1950 and 1954

18/8/Mo or molybdenum bearing steel contains, in addition to the chromium and nickel of austenitic stainless steel, 2 per cent to 4 per cent of molybdenum. In this group are the steels known as 18/8 SMo (American) and FMB (En.58J) Introduced to British surgery only since World War II and now standard.

Vitallium (syn. Vinertia) These are American and British trade names for the same alloy Not a steel at all. The bulk metal is cobalt. Introduced to surgery at some time after 1937

* Sir William McEwan was having plates made in 18/8 and screws of chrome steel for his own use as early as 1924

† In *1954* the last manufacturer to come into line for plates and screws changed over to *18/8/Mo*. Some Kuntscher nails continued to be made in FSL until 1956—as far as can be ascertained without harmful results.

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CHAPTER 4

PLASTICS

A KENNAWAY

GENERAL INTRODUCTION

PLASTICS FORM a group of materials which is occasionally to be found in for example shellac (Midvani 1954) and gum but most commonly th obtained by synthesis of one or more chemicals to form a polymer A pol a substance each of whose molecules is composed of a large number of linked molecules. This definition can be narrowed further to cover only those pc which flow plastically at one stage or another of their fabrication

For the most part plastics are organic substances—that is to say they ar on carbon compounds. It is not easy to isolate them rigorously by def particularly from the rubbers In fact in recent years, the distinction b the rubbers which are also polymers and the plastics has become more b Not only have many varieties of synthetic rubber been made but their cons have become components of many plastics which in turn can be used as ad to rubber itself Generally however rubbers are elastic materials, that will change their shape under load and tend to recover their original shap the load is removed (This is because their molecular configuration is such th tend to return to the condition of maximum entropy, that is to take up the p of maximum internal disorder) This tendency increases with rise in temp and so the elasticity of rubber increases with it plastics, on the other h not behave in this manner They like metals, deform elastically under init to the yield point and then deform plastically undergoing a permanent de tion. With increasing temperature the transition from elastic to plastic de tion will occur at lower loads. With plastics this change occurs at muc loads than with metals at much lower temperatures. At temperatures 100° C. plastics yield irreversibly under moderate loads This property plastics to be formed into shapes at moderate temperatures and with litt using simple processes and equipment. These same mechanical conside of course, render plastics weaker than metals although they are compa strength with many other materials, as can be seen in Fig. 22.

Plastics in general have interesting physical and chemical properties. pure containing no fillers, reinforcements or pigments, they are naturally specific gravity (between 0·9 and 1·6), transparent, easily coloured, e insulators both electrical and thermal and they are inert chemically to range of conditions and reagents It is not surprising, therefore that d of many components have found it worthwhile to seek methods of over their limitations in order to use this class of materials

Designing in plastics is an art and a science still at the stage where, a case of many other materials such as rubber glass, and the new metals t and zirconium, the best results are to be obtained by considering the app of the article as a complete problem demanding the full collaboration

product user designer and raw material specialist. This is partly because most industrial designers and engineers have not yet acquired the "feel" of plastics technology to the extent that the "feel" of metal working has soaked itself into their technical subconscious. It is also partly because information about the properties of plastics cannot yet be so accurately and usefully formalized as to publish it in tables and general data books, for use in all cases without further consultation. This will sometimes be possible but the expert advice of raw material manufacturers can be used to advantage particularly where the product must operate under conditions near the limit in any direction.

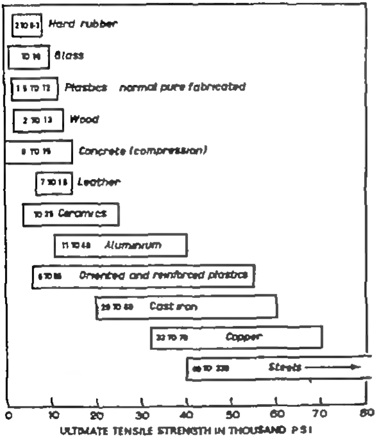


FIG. 22. — Comparative strengths of various materials.

In the context of the present book it is important to remember that plastics were not conceived specifically for surgical use. Whilst the list of properties of a given basic material may suggest that it may be perfectly safe to place the plastic in the human body it may in fact be unwise to pick any commercially available embodiment of the basic formulation. There may be hazards present in the material minute additions such as the remnants of catalysts and surface active agents—essential for the manufacturing process, which might be harmful or others such as lubricants, anti-oxidants, plasticizers or pigments which are added to give certain properties desirable to the industrial fabricator of the raw material or possibly free unreacted molecules of the components of the plastics themselves. All these things will have been carefully checked by reputable manufacturers to see

that their product is not toxic or generally hazardous in its usual range of industrial duties (Harris, 1953) However the materials may well be harmful especially if inserted into the body for long periods The responsibility for checking this clearly lies with the potential user It is not possible to indicate all the danger points because each substance in detail is part of the manufacturer s recipe which is not normally required to be disclosed It follows that materials which may lie in the same competitive group may have different trace additives present which will have to be checked individually Finally it is important to be certain of the identity of a particular material

The purpose of the foregoing is to point out the possible dangers, particularly of using plastics from casual sources of supply But whilst the purity of plastics may not always be quoted quite to pharmaceutical standards, they are at least as free from impurity as such natural materials as leather and fibres Whatever else may be said of these plastic products of the chemical industry at least the analyses have been carried out with so much care that trace elements are measurable down to a few parts per million Furthermore, their composition can be fully defined and maintained reasonably constant

Plastics are usually classified into two types. The thermosetting types set hard on polymerization, which normally takes place by heating, and are then allowed to cool. They do not soften again on reheating, but only degrade and char Such plastics are sold as incompletely reacted liquids or powders and are finally polymerized and moulded into their final shape in a combined operation, although of course, they can be further machined.

The thermosetting liquid resins are also used to impregnate materials like paper cotton and other fibrous textiles, vegetable waste like wood pulp and glass fibre. The resin is used to bond the impregnated materials together and when set hard the whole becomes rigid These materials are usually called reinforced plastics and derive their strength largely from the strength and arrangement of the filler within the mass and also from the shape of the structure.

The thermoplastics, on the other hand, soften on reheating without loss of quality and are therefore sold as polymeric liquids or solids Their fabrication is a separate operation

In these materials the long, chain like molecules lie side by side, albeit coiled randomly like caterpillars In the thermosets cross-linking takes place between atoms of the molecules at right angles to the main axis of the molecules, as if the arms and legs of the caterpillars grasp each other Thus a thermosetting material has internally fewer " degrees of freedom " and is therefore more rigid than a thermoplastic It is also less elastic and, although generally it can support greater stresses, if deformed too far it will break its molecular and atomic bonds irretrievably rather than yield plastically and thus it will be liable to shatter under shock Thermoplastics can be strained further under load without fracture and will recover better when the load is removed.

Some materials lie between the two types, and their molecules may have only a few side-chains and will be only partially cross-linked These materials therefore still largely exhibit the heat sensitive properties of the thermoplastic materials

The properties of plastics, as of every other substance, stem from their atomic and molecular structures A knowledge of their basic structure was required in order to make plastics, except by accident. More is probably known of their

structure and of the link between structure and properties of plastics than of most other materials. Plastics are available with many different chemical structures and offer different combinations of properties, which must be considered when selecting the right plastic for a particular duty. To some degree certain modifications can be designed in order to change the behaviour of the material.

Modifications taking place today in plastics have many forms. Polymers of more than one monomer are called copolymers or interpolymers and give new materials with properties different and possibly superior to those obtained by polymerizing the constituents by themselves. Other non polymeric, materials are added and frequently improve the physical and fabrication properties. The polymers themselves may be subjected to irradiation by nuclear bombardment, which has the effect of cross linking thermoplastic materials and making them stiffer and increasing their temperature resistance and mechanical properties. By stretching the plastic the mechanical properties of randomly oriented polymers may be improved. The increasingly familiar synthetic fibres like nylon and Terylene are obtained by this means. The atoms situated on the branches in the molecular chain may be designed by the chemist to be more regularly situated producing polymers which are named 'isotactic' and which can be crystallized. By comparison with the polymers in their amorphous state their tensile strengths and other properties are improved and it is also possible to make film and fibres from these materials. By all these processes the properties of plastics are being continually widened and improved.

Their unique properties or combination of attributes have widened the uses of plastics in surgery in the past few years. The best applications require that the materials are only selected after full consultation between the surgeon, the engineer and the material specialist.

As will be clear from this and later chapters, plastics, in spite of the chemical inertness of many, are not suitable for making components which are to be subjected to abrasion or to stresses which are high for plastics but which may be quite moderate by the criteria of normal metal design. Internal prostheses such as the Judet type have, not unexpectedly from an engineering standpoint, often failed for such reasons (Scales and Zarek, 1954).

THERMOSETTING PLASTICS

These are amongst the earliest plastics available, and form about half of the total plastics production of Great Britain. In the United States of America thermoplastics predominate. Their ability to be moulded rapidly and cheaply, particularly with metal pieces inserted, allowed the mass production of many items vital to the electrical, telephonic and radio-communication industries. These developed rapidly in the 1930s and without the widespread use of the thermosetting plastics progress would have been retarded. Their chief surgical uses have so far lain in the manufacture of prostheses for the lower limbs.

Medical applications include the use of cold setting resins for encapsulating preservation of anatomical specimens and for ascertaining the shape of various organs in pathology by filling them with liquids, which then set solid in position (Scales, 1950). They are also useful for casting into simple moulds. As reinforcing materials with fabrics they are useful for making shapes by machining from block

or by dipping cloth in resin solutions and shaping after the manner of plaster of Paris bandages

They are available as powders consisting of a polymerized resin and a filler such as wood flour in roughly equal proportions These powders are used to make mouldings The familiar Bakelite a phenolic resin (Whitehouse and Pritchett 1955) named after Dr Baekeland its inventor belongs to this class and is amongst the oldest established of the commercially used plastics It consists of cross linked long-chain molecules which give a three-dimensional interlocking structure which is responsible for its rigidity infusible and insoluble properties

The thermosets are also available without fillers as pure resins which can be used as a paint lacquer adhesive or as a bonding agent to form laminated structures containing textiles paper or glass as reinforcement Lamination and impregnation are extremely important as they give rigid structures of complex shapes with very simple techniques and equipment Some can also be blown to give expanded lightweight materials

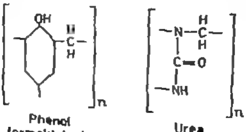
Types

Thermosetting powders and resins can be subdivided into six main groups

Groups			*Applications*
Thermosetting plastics	Phenolics	Phenol formaldehyde Resorcinol formaldehyde Phenol furfural	Powder and resin Adhesives Powder
	Aminos	Urea formaldehyde Melamine formaldehyde	Adhesives Wide colour range and good electrical properties
	Anilines	Aniline formaldehyde	Powder
	Polyester	Ester of allyl alcohol	Laminating (with fabric reinforcement)
	Alkyds	Alkyd compounds	For moulding
	Furanes	Furfural alcohol	Coating

Structure

When completely cured, phenol formaldehyde and urea formaldehyde consist of chains of molecules which are cross-linked to form a rigid structure which may be shown



Phenol formaldehyde

Urea formaldehyde

Manufacture of resin

Phenol or urea or melamine are respectively combined with formaldehyde in a condensation process, a viscous liquid resulting. Moulding powders are formed by mixing and grinding of fillers and pigments

THE THERMOPLASTICS

Reconstituted Plastics

These are not fully synthetic materials since their molecular structure is that of natural but modified raw materials The two main groups are based on cellulose and casein (Collins, 1952) These plastics are mostly used for decorative purposes since their mechanical and chemical properties are mostly poor In the early days, with little else available, cellulose plastics were used for prostheses because of the ease of fabrication and colouring to resemble flesh tones (Soft polyvinyl chloride is now used a great deal for this purpose.) Solutions of cellulosics are still valuable for film forming and impregnation Whilst they appear to be losing ground to other thermoplastics, the stimulus of technical competition may lead to useful improvements in properties and uses

Cellulose Plastics

Cellulose can be modified to give several plastics, of which the most familiar are cellulose nitrate (celluloid) invented by Parkes in Great Britain in 1869 and regenerated cellulose (viscose) and the acetates which are also the bases for so-called artificial silks (rayon)

Nature of polymer

General physical properties

These materials are transparent unless coloured In the solid state they are easily machined and fabricated Adhesives containing solvents for cellulosics can be used to give strong joints Their strength depends on the degree of substitution of the original cellulose molecules and largely on the amount of plasticizer present.

Cellulose nitrate has a very high impact strength, however and all of the cellulosics have good elongation at fracture

Variants

Each of the polymers may vary in proportion, depending on the condition of the cellulose, the kind and relative amount of the ingredients and on the time temperature and agitation of the reaction For instance, varying degrees of nitration and acetation are possible This is important since some nitrate grades are explosive Plasticizers can be added their types are numerous. Camphor is the usual one for the nitrate material Colouring and plasticizer are usually incorporated on mixing rolls or by kneading.

Available forms

These materials are usually available in block, sheet, film or moulding powder form Most can be easily fabricated further by machining, powdering or heat

shaping. Cellulose nitrate is mixed with a solvent before processing on account of its heat sensitivity which also permits it to be moulded

Some types, particularly acetate and nitrate are available in solution form which allows them to form films *in situ* and to impregnate fibrous materials to form reinforced flexible structures Metal articles may be dipped to give protective coatings The solvents are usually highly inflammable

The cellulosics can be extruded to give film sheet tubes or sections. Filament yarns which are the basis of the rayon and viscose industries are also made from acetate Apart from regenerated cellulose and nitrate all can be moulded

Polythene

Polythene is obtained by polymerizing the gas ethylene The polymer is available in a range of densities of which the lowest density is the original material and available in quantity The remainder are of recent development and supplies are at the moment more limited Work on higher density materials is progressing rapidly and the position at the time of writing may soon be outdated Broadly speaking, higher density polythenes give some improved properties such as high stiffness and softening point, taking the material closer to nylon in performance but occasionally with some loss of property in other directions such as an increased tendency to degrade by oxidation

Polythene is a particularly interesting substance to the surgical worker because of its relative inertness and its ease of fabrication which make it available in many forms.

Nature of polymer

General description

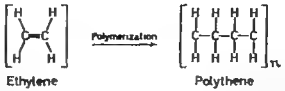
Polythene has a slight waxy feel and is warm to the touch it is not well wetted by water It is transparent in thin films and, when molten translucent in thicker sections and white like pure paraffin wax in really thick sections liquid levels can generally be seen through most tube thicknesses. It is generally odourless and is tasteless In the solid state it can be machined, cut, welded, and heat sealed. It is difficult to stick things to it, but pressure sensitive adhesives based on polyisobutylene can be used, although they remain tacky Deposits do not form readily on it thus tubes do not block easily It is referred to in Great Britain as polythene in the United States of America it is called polyethylene

Structure

Polythene has the simplest of all structures and is composed of linear molecules made up of repeating methylene units the molecules contain many branches but are usually depicted as $(-CH_2)$ The molecular weight varies but is usually between 15 000 and 45 000 in low density and up to 1 000 000 in high density At normal temperatures the material contains both amorphous and crystalline components, the ratio increasing with the temperature until the material is fully amorphous at the melt point.

Manufacture

The gas ethylene is polymerized in the presence of catalysts to give polythene The step may be depicted thus



With the standard high pressure process the material comes down as pure poly thene, a molten viscous material which is solidified and granulated into small units roughly ⅛ inch side. In general no harmful catalyst remains, but certain polymer variants will contain, particularly for use as cable, pipe and splints, a very small proportion of anti-oxidant This is necessary to prevent the degradation which will occur if unprotected material is held at elevated temperatures in subsequent processing. The new high density polymers can also be made by alterna tives to the normal high pressure process. In one such, ethylene gas is bubbled through a liquid containing catalysts. Polythene now comes down as finely divided powder from which the catalyst and other elements have to be washed. It is too early to say whether the powder which is subsequently remelted and granulated, contains harmful residues or not, since exhaustive tests remain to be done. Yet another however leaves no catalyst residue this process is operated in the United States of America

Variants

Polymers in general use have melt index numbers attached which correspond only to their molecular weight, the numbers generally available being 0 2, 2, 7 20 the lowest number having the highest molecular weight and stiffness. Further more, by varying the process conditions, materials with a slightly different balance of properties may be obtained These may be chosen to give a balance suitable for particular fabrication methods, and thus there may be a type for general use film use, bottle blowing, and so on. Plasticizers are not normally added to poly thene, so that there is no problem due to side effects from this cause.

Available forms

Polythene may be processed in many ways. It can be extruded to give filaments or tubes, or solid sections of complex shapes. It may be used to insulate wires or cables.

It can be moulded to give blocks, sheets and small articles such as bottles. It can be extruded to give thin films which are available in various thicknesses and other materials and films can be coated or laminated with it. It can be sprayed over metal articles, which can also be dipped into it to give chemical protection. Thus it is a material of great versatility Examples of its medical uses are

Filaments—woven into fabrics and may be drawn to threads with about a quarter of the strength of nylon
Tubes—for drainage of the body

Wires—for insulating electric leads to instruments
Mouldings—can be shaped to give supports used in plastic surgery bottles for holding fluids squeeze bottles for dispensing.
Films—may be used for packaging medical supplies and for internal repair work
Sheet—splints

A type containing finely divided carbon black, up to 2½ per cent is sold for tube and pipe manufacture This is to protect the product from ultra violet attack but this material would not normally be considered for internal medical application It is also available in many colours the pigments used will have to be checked individually for internal use There is no detectable free ethylene in polythene in any fabricated form.

Polyvinyl Chloride (P V C)

Vinyl chloride was first polymerized in the laboratory in 1838 but remained an academic curiosity until the 1930s, when it attracted attention in Germany P v c. to which it is commonly abbreviated, vies with polythene as the world s most abundantly used plastic.

Nature of polymer

It is most commonly known when softened with the addition of a plasticizer thus rendering the material rubber like at room temperature In this form it performs duties similar to leather rubber and rubberized materials Without the addition of a plasticizer it is a hard, horn like material at room temperature, of relatively high specific gravity for a plastic (1 35–1 55) slightly yellow and translucent Like polythene it can be machined but is more difficult to process in other directions such as welding and moulding and can only be heat sealed by the use of radio frequency heaters It has excellent mechanical properties and can be cemented to metals. Its resistance to attack from inorganic environments is similar to that of polythene but it resists organics rather better Its upper limit of working temperature is about 60° C. and it is self-extinguishing when set on fire and is there fore generally regarded as non inflammable

Structure

P v c. normally has an amorphous structure composed of linear molecules of the form $(-CH_2-CHCl-CH_2-CHCl-)$ and has a molecular weight of about 50 000 which can be varied over a wide range by the degree of polymerization

Manufacture

Vinyl chloride monomer $CH_2=CHCl$ is a gas and is polymerized by heating in presence of a catalyst in a liquid which is usually water There are two normal types of polymerization, granular and emulsion Both types yield a powder the former consisting of small hollow incomplete spheres (xenospheres) made up of tiny powder grains and the latter giving a powder of the size roughly equal to the smallest grain making up the xenospheres of the former The granular is slightly more difficult to process but yields the purest polymer emulsion polymers generally containing some catalyst and other residues which survive the washing and drying stages which follow polymerization

Variants

Polymers are available with different molecular weights which are given in terms of a K value K50 corresponding to a molecular weight of 45 000 and K65 equivalent to 60 000 The higher the molecular weight the better the mechanical properties and chemical resistance but the harder they are to process. Com promise is usually sought and materials of K value lower than 65 are normally used

Further ease of processing is also obtained by interpolymerization with other materials such as vinyl acetate to give copolymers which are also becoming avail able in quantity Other copolymers are of the butadiene/acrylonitrile/styrene type, commonly used in synthetic rubber Such interpolymers are easier to process because of their lower softening point, but the material becomes more rubbery Methacrylate polymers are also being added to p v c. to give new materials with interesting properties such as high transparency and strength. Other additives are lubricants and stabilizers to prevent the degradation under the action of heat to which p v c. is so prone during fabrication operations Many of these stabilizers are toxic and prevent the use of these materials in the food industry These additives may also appear in plasticized p v c., which has markedly reduced mechanical properties and chemical stability but is very easy to fabricate.

Plasticized p v c. is available with a wide choice of formulation suited to par ticular duties and, as has been said above, a particular formulation is often selected because of some particular advantage which it possesses over rubber for the duty

In addition to plasticizers, fillers such as cork, silica, chalk and clay may be added to certain specific grades. These are added chiefly on grounds of economy and to improve abrasion resistance or resilence for flooring. By adding wetting and dispersing agents the material can be obtained in the form of pastes which are used to make simple mouldings Foamed or expanded material resembling sponge of small separate regular cellular construction can be obtained These have excellent insulating and cushioning properties

Available forms

Rigid p v c. is normally available as a powder in blocks for further machining, or in sheet form which can be shaped at relatively low temperatures (100° C.) by vacuum or slight pressure. Some film is available with excellent mechanical properties, and some flexible clear sheet

Mouldings can be obtained by compression and p v c. can be extruded, given care, into a large variety of shapes. Pigments can be added to give a wide range of colours.

Plasticized p v c is available in the following forms

- *Paste*—which can be moulded by hand or by simple methods and is used to make flesh-like prostheses
- *Sheet* (flexible and sometimes translucent) for protective clothing. Surgical uses reported include that of repair work.
- *Coated fabrics* of great variety—a wide use in upholstery and decorative and protective duties
- *Filaments*—for weaving into textiles, which are classed as non inflammable
- *Tubes* and *wire covering*

Other vinyls

There are several other plastics of similar structure to polyvinyl chloride Of these polyvinyl alcohol is sometimes reported in medicine as an aqueous solution in pharmacology Polyvinyl acetate yields a solid plastic of some value It is occasionally used in the form of film or tube and is water soluble Interpolymers of polyvinyl acetate and polyvinyl chloride are commonly used They are far easier to process than pure p v c. and yield quite ductile and tough plastics, although their mechanical properties are much lower than those of p v c

Polyvinyl pyrrolidone

This material has been briefly described by Fishburn (1955) It is used as a plasma substitute in an aqueous solution of material fractionated to yield a closely controlled molecular weight and also as a complex with iodine It has been claimed that the combination may be used safely even internally

Nylon

Nylon is the result of many years of research into the principles of polymerization by one of the greatest polymer chemists—W A Carothers. It is a name given generically to a polyamide group of thermoplastics obtained by a polycondensation, usually of two radicals, rather than by the usual additional polymerization

Nature of polymer

It is certainly the strongest of all plastics available at the present time and can be obtained in granule form for moulding as well as the familiar yarns, textiles and monofilaments which are large diameter single fibres.

Its natural colour is yellow and slightly translucent—the yarns are normally made white and opaque by the addition of titanium dioxide pigment. A full range of colours is possible It has a high melting point—over 250° C —and retains sufficient strength for the working temperature to reach 120° C. It has excellent mechanical properties and can be very easily machined and fabricated Its chemical resistance to alkalis and to most organic liquids is good, but it is attacked by acids. Nylon, like all plastics with OH COOH or NH groups is hygroscopic and thus its electrical insulating properties are slightly reduced its moisture absorption is far lower than that of many natural materials. Cementing is possible with special adhesives and nylon can be solvent bonded to itself using formic acid

Structure

Many types of nylon can be made they are usually classified by the number of carbon atoms which are distributed on either side of the NH group Thus Nylon 66 polyhexamethylene adipamide is the most common of the nylons and has the formula

$$(NH - (CH_2)_6 - NH - CO - (CH_2)_4 - CO -)_n$$

and the molecule is protein like in structure with amorphous and crystalline phases whose ratio varies with temperature and mechanical treatment and affects the properties.

Manufacture

Nylon is made by combining a diamine and a dibasic acid to form a salt which is then polymerized. Nylon 66 is obtained by condensing hexamethylene diamine with adipic acid. After polymerization the nylon forms a very viscous liquid and is evacuated from the vessel quenched and chipped into moulding material or processed into yarn form.

Yarn and monofilaments are made by pumping molten polymer through a multitude of holes in a spinneret plate, which is then quenched and drawn The drawing process simply means pulling the yarn or monofilament so that its diameter is reduced by ratios extending to 5 1 or 6 1 After thermal conditioning, the changes in the fibre, such as increasing the crystalline-amorphous ratio, straightening the molecules along the axis of drawing—orienting as it is called—become irreversible and the fibre can now withstand extremely high tensile stresses in the direction of draw—up to 25 tons/in.^{2} as good as some alloy steels. This drawing process has to be done below the melting temperature of the polymer for these effects to occur The draw can be varied cyclicly to give tapered thread instead of one of constant diameter

Variants

By varying the initial components, nylons of different properties are obtained. For example, by taking the next of the dibasic acids—sebasic—together with the same diamine as Nylon 66 another nylon, 6–10, is obtained, generally similar but with slightly improved resilience and moulding properties Single component nylons are made by condensing amino acids such as caproic acid forming Nylon 6, sometimes known as caprolactam, which is in vogue in Europe

Plasticizers can be, but are usually not, incorporated. Mixtures of the separate nylons and copolymers are becoming available for special purposes.

Available forms

Nylons can be extruded and moulded and most plastics processing methods can be applied to them. Thus they are available as

(*a*) Yarn cloth.

(*b*) Monofilament for sutures, known as Sutron and available in a range of diameters.

(*c*) Films which can be made by extrusion of the melt or by evaporating solvent from a solution of polymer These films are generally transparent and tough, particularly when drawn, and some have other interesting properties such as high moisture vapour permeability

(*d*) Nylon solutions in which articles can be dipped to give protection against abrasion or chemical attack.

(*e*) Moulded sheet and blocks which can be machined shaping is difficult because of the high softening point and moulding by injection or compression under heat is normally better

(*f*) Moulded articles such as bottles and hypodermic syringe cylinders having high strength and which can be sterilized.

Nylon has excellent wear properties and can be run almost dry in contact with itself and makes excellent silent moving parts.

Terylene

Terylene is the familiar name for the fibre-forming polymer polyethylene terephthalate, discovered in 1941 by Whinfield & Dickson in Great Britain in the laboratories of the Calico Printers Association. It is complementary to nylon and is becoming widely used as a textile and as a yarn. It is also available in film form, which has certain useful properties.

Nature of polymer

It is a thermoplastic polyester formed by the combination of ethylene glycol and terephthalic acid. Only the film known as Melinex in Great Britain and as Mylar in the United States of America will be described here. It is available as a pure material, and also with additives to increase its slipperiness; this latter form is less transparent and will probably be less interesting for surgical purposes. The film is of interest in that it is extremely strong, relatively inert and can be sterilized. It has been used in making dressings as a finely perforated thin film which largely eliminates adhesion between the wound and the dressing.

Manufacture

The polymer is melted and extruded from a die and the molten film is quenched rapidly. This gives an amorphous material which is fairly strong but is unstable. The film is then heated above 80° C, drawn in two directions when the brittleness disappears, and the film becomes very much stronger. In the third stage the drawn film is heated to about 20° C while it is geometrically restrained from contracting. It then becomes far more crystalline and substantially stable dimensionally up to 200° C.

Melinex is normally supplied after passing through all three stages as a plane oriented crystallized film which is extremely strong, some types being capable of resisting stresses in the range of 7–20 tons/in.^{2} For experimental purposes, however, film from the first and second stages may be useful. After the first stage heated amorphous film is useful for blowing into shape and after the second it will contract considerably unless restrained. This property is useful for packaging articles where exclusion of air is necessary.

Available forms

Standard film contains no additives such as plasticizers. It is available in a range of thickness from ½–5 thousandths of an inch. It is difficult to make strong seals with itself but the film can be stuck to many other materials.

Polymethylmethacrylate

This polymer is the best known of the acrylic group. It is most familiar as flat sheet (for example Perspex, Plexiglas, Lucite) but is also available as a moulding powder.

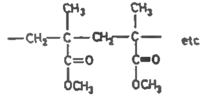
It has been much used in bone surgery with particular success where it is not subjected to high stresses or abrasion.

Nature of polymer

The special features of this material in all its forms lie in its superb optical qualities combined with relatively high strength flexibility and its ease of handling and manufacture which are typical of a thermoplastic In many European languages it is aptly known as organic glass It is also chemically inert in presence of strong alkalis and weak acids but is attacked to a varying degree by a number of organic materials and strong acids. As regards plastics, its resistance to shatter is fairly good and its softening point high at 105°–120° C. It is not classed as non inflammable.

Structure

Structurally the polymer is composed of linear molecules of the form



Polymethyl methacrylate

Perspex has a relatively high molecular weight of 250,000 whereas the moulding powder has a somewhat lower one in order to permit easy flow in moulding processes.

Manufacture

Distilled monomer is thickened and poured into glass cells and polymerized by heat. A catalyst is normally added The resulting sheets are stripped from the glass, papered and edge trimmed Sheet is available in a wide range of solid and translucent colours, made by adding colours to the thickened monomer The moulding powder is made by heating a mixture of monomer granulating and stabilizing agents in water within a jacketed vessel. It comes down as a powder which has to be washed and dried In this form it is often used as a base material to make paints, lacquers and for coating and impregnating paper and fabrics. Colours may be added and the powder converted to rather larger granules roughly ⅛ inch in diameter for moulding.

Variants

Both sheet and moulding materials are available with some plasticizer added—usually dibutylphthalate—in order to improve the flow properties in later processing, but at some sacrifice in heat resistance.

Special tinted powders are available for dental purposes. Copolymers of methyl methacrylate with ethyl acrylate are also manufactured.

Since methyl methacrylate is a most reactive monomer it is hardly surprising to find it in association with numerous other materials such as butadiene, when it ceases to become an organic glass, but acquires radically different properties. It may play the part of a synthetic leather or rubber with interesting properties or as a paint base or paper coating material when in latex form.

It can also be reacted with p v c on which it may have a softening effect and give increased transparency One variety of such copolymers is the novel block copolymer in which long chains of p v c. molecules are broken by mechanical

working and long chains of methyl methacrylate molecules are polymerized alongside the p v c chain

Thus instead of the random arrangement of copolymerized molecules of two components AABABAABBAA we have A-A-A-A-A-B-B-B-B-A-A-A-A-A with very different physical and chemical properties This new type of material is made by a mechanical-chemical process involving the mechanical rupture of the molecular bonds This principle of macromolecular formation is not limited to the two components described above and will probably be widely applied to polymers generally

Available forms

The polymer is normally available as a sheet or block for subsequent shaping or machining. Mouldings can be made in large variety and endless sections can be extruded. This includes rod tube and flexible stretched foil

Similar materials

Most of the above applies also to polystyrene, which is the only other plastic with the brilliant, transparent optical properties of methacrylate Styrene, which at the time of writing is slightly cheaper by comparison, has inferior properties in several directions, notably chemical resistance, and resistance to shock loading and sunlight It has a different refractive index from methacrylate As with methacrylate, styrene is also a component of rubber and paint synthesis

FLUOROCARBONS

All the plastics which have been reviewed so far have been hydrocarbons The carbon atoms which are linked together by polymerization or condensation to form the main molecular chain have hydrogen as well as other atoms attached to their other branches In the fluorocarbons fluorine replaces hydrogen either partly or completely This new group opens a whole new field. Two materials in the class have been synthesized and are available in factory quantities The first is one in which four carbon atoms are all linked to a fluorine atom and is called polytetrafluoroethylene (P T F E.) and the second has one fluorine atom in four replaced by a chlorine (KEL-F)

Nature of polymer

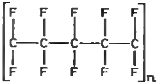
The chief attributes of P T F E. are its chemical inertness excellent electrical insulating properties, high fusion and working temperatures, and its peculiar non adhesive and self-lubricating qualities These unique properties have naturally not been obtained without tribute to Nature in this case taking the form of an expensive route and difficult processing conditions, thus limiting the applications

The excellent properties of the fully fluorinated P T F E. lose a little in the trifluoro-monochloro material (KEL F) but the processing conditions become slightly easier

Remarks below will be confined to P T F E., known in the United States of America as Teflon and in Great Britain as Fluon.

Structure

The structure can be represented by



and the polymer is crystalline. It is thought to contain submicroscopic crystallites in an amorphous matrix, the amorphous–crystalline ratio being capable of variation by mechanical and thermal action.

Manufacture

An intermediate gaseous product—difluoromonochloromethane—is prepared from chloroform and hydrofluoric acid and is pyrolized in tubes at high temperatures to give the monomeric gas tetrafluoroethylene This is purified by scrubbing and fractionation. Polymerization is carried out in an autoclave in an aqueous solution with a peroxy catalyst. Solid P T F E. now results as a flocculent powder which has to be reduced to a more uniform particle size about that of granulated sugar and dried

The resulting polymer contains no free fluorine or catalyst residues. The powder does not melt on heating like the other thermoplastics and cannot therefore be moulded in the same way The powder has to be sintered and handled in the manner of powdered metal technology The powder must first be compressed in a mould, to give a preform which has nearly all air excluded from it and which is strong enough to be handled It is then placed in an oven and heated at 360° C. for about 1½ hours, when contraction takes place The oven must be well vented to the atmosphere, since poisonous fumes are evolved. The moulds may be made to the desired shape or into blocks which can then be machined further or from which a continuous thin ribbon can be shaved. It is almost impossible to make the material adhere to anything else, though recently a promising method has been evolved

Variants

A choice of molecular weight is not possible. Fillers can be incorporated, chiefly in order to lower the cost but at considerable loss of the basic properties Polymer can be pressed into porous metal and sintered to give protection and good bearing properties. The main variant is obtained by varying the polymerization to give a suspension of small Fluon particles in water This solution can be sprayed on to articles, which can alternatively be dipped in the solution. They are then baked in an oven at 360° C., when a smooth unbroken film is formed with a fair adhesion force Such articles now enjoy the full protective and non-stick properties of Fluon and find many applications for electrical food and other purposes where high temperature duty or cleanliness is particularly required.

Available forms

From the two basic materials described above, the powder and the dispersion a multitude of forms can be made.

The powder can be sintered to form a myriad of mouldings mostly used in the chemical and electrical industries, such as gaskets stop valve seats and packings and electronic components It may also be extruded by a sort of continuous sintering process to form rod tubes, wire coverings and so on

The material has poor recovery and this loss of elasticity coupled with its tendency to creep under load particularly at high temperature limits some of its applications. In these cases the less fully substituted type KEL-F is preferable since it has a greater degree of recovery

SILICONES

In the list of thermoplastics is to be found another remarkable group in which the main molecular chain is composed, not of carbon atoms, but of alternate silicone and oxygen atoms Organic atomic groups are attached to the side chains of the silicon atoms, and variations in composition of these groups can be made, with consequent changes in properties.

This group of plastics owes much to F S Kipping, Professor of Chemistry at Nottingham University These materials are made in Great Britain under licence.

Nature of polymer

General description

A large variety of products is based on the silicon–oxygen system, such as fluids resins, greases and elastomers. Certain properties are held in common by them all the most interesting being their extremely good stability to heat, cold and chemical attack. Only the elastomers are solids and should really be considered as synthetic rubbers with remarkable working temperatures—ranging from 150 C to −90 C. and being inert to many media attacking normal rubbers.

The liquids are also interesting in that they are water repellant and have a low surface tension, and are frequently used for waterproofing. Their uses in medical work have been well covered elsewhere (Hopkin and Williams, 1954) Compounds are made by adding finely divided silica Lubricants and greases are made by adding special soaps or carbon black to the liquid Silicones are odourless and tasteless

Structure

Silicones may be represented by the general formula

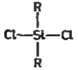
$$\left[\begin{array}{ccccc} R & & R & & R \\ | & & | & & | \\ Si & -O- & Si & -O- & Si \\ | & & | & & | \\ R & & R & & R \end{array}\right]_n$$

where R represents an organic group normally phenyl or methyl.

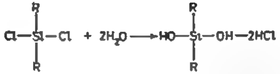
Manufacturing method

A full account is contained in a book (McGregor 1954) by one of the original workers on these materials, and from which the following is taken

Sand is treated with chlorine at 1,000 C to give silicon tetrachloride, which is a liquid. This is reacted in several ways so that one or more of the chlorines is replaced by a carbon group such as methyl, ethyl or a phenyl. Thus we may have two replaced



as the carbon-silicon bond is not affected by water If the compound is dripped into water silica will not be regenerated. In fact a silicone arises.



The OH groups continue to split with water and long chain silicone molecules result, giving a liquid which is the starting point for other forms of silicone.

Available forms

Medical applications for these new materials are probably numerous and clinical tests are still proceeding. Amongst uses reported are barrier creams alternative excipients to paraffin and vegetable oils in ointments and liniments as anti-frothing agents and as aerosols.

The silicone rubbers resemble other rubbers except for their wide temperature working range and their higher degree of inertness.

ISOCYANATE-BASED POLYMERS

A relatively new class of polymers based on isocyanates can be made by reacting them with compounds such as hydroxy amino- and carboxyl (Dombrow 1957 Simonds, Weith and Bigelow 1948) They are structurally similar to nylons.

Most experience has been gained in Germany and the most commonly available of the three types, polyurethanes, polyamides and polyureas, is the first. The most dramatic of its uses is as a foamed material with a wide range of flexibility and density The flexible foams normally have an open, inter-connecting cellular structure and in the stiffer materials the cells are discrete. These foams find surgical applications as cushioning materials. These interesting plastics will undoubtedly find wider applications as experience and supplies increase.

It is difficult to describe concisely the type of product in this group since they are becoming rapidly more numerous, together with a widening range of applications.

Nature of polymer

Structure

Polyurethanes are formed by reacting polyhydroxy compounds with poly isocyanates Thermoplastics are obtained with the di-isocyanates and cross-linked types by the higher compounds, for example meta-toluene di-isocyanates and ethylene glycol

Polyureas are obtained from the reaction between polyamino compounds with polyisocyanates—for example meta toluene di isocyanate and ethylene diamine

Polyamides are prepared by reacting polycarboxyl acids such as adipic acid with the same isocyanate as above

Available forms

The urethanes and other isocyanates are available as adhesive resins, coatings and rubber-like materials, as well as in the familiar foam form The foam is available in block form, which is also offered as sliced sheet It can also be foamed *in situ* to become part of a structure

The components of these polymers when mixed together can only be kept for a short time and they are toxic in some cases at processing temperatures above 60° C Consequently the tendency is for these materials to be made by specialists, rather than by the users.

PROPERTIES OF PLASTICS

Mechanical properties

The designer can confidently expect plastics to compare in strength with such materials as natural fibres and textiles, leather wood, plaster and rubber and indeed to show superior performance under certain conditions.

They are, however nowhere near as strong as steels (*see* Fig. 22) in spite of over eager attempts to prove the contrary by mathematical manipulation of quantities and presenting them as strength–weight ratios and the like It may well be in marginal cases that a given degree of support can be achieved with less weight, which will be useful to the wearer but, in general, plastics must be ignored in applications which require the tolerance of high stresses by the component.

It will be clear from the previous pages of this chapter that strength is not an invariable property Safe working stresses cannot be stated baldly without qualification (Fig. 23) This is the same practice as with metals but with these the normal environment conditions often do not cause large variations, and large safety factors are possible. Strength varies simultaneously with such properties as temperature (Fig. 24), chemical environment,* molecular weight (Fig. 25) structure and condition of the polymer (Fig. 26), time and type of loading (Figs 27 and 28) and, in the case of hygroscopic polymers, with humidity

For these and other reasons the data in Table I must be treated with caution It is again suggested that plastics manufacturers should have an opportunity to comment on particular designs, especially when limiting conditions are thought to rule

The modulus of elasticity of plastics is low compared with that of metals in other words in a given loading condition plastics will deflect (elastically) more—for example about ten times more than steel, but about the same amount as wood.

Physical properties

These are also shown in Table I and it must be remembered that these too vary with conditions particularly if fillers are used.

* Chemical attack will tend to weaken plastics which are subjected to load by causing cracks, or penetration of the surface. This form of weakness is referred to as environmental cracking or embrittlement and is akin to stress corrosion in metals.

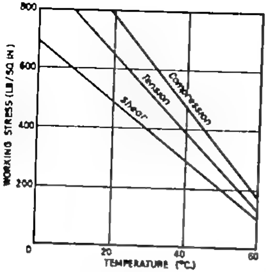


FIG 23 Working stresses at continuous load unplasticized p v.c.

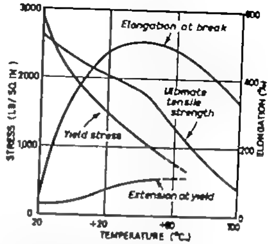


FIG. 24 —Effect of temperature on mechanical properties. Short time tests, Grade 2 Polythene.

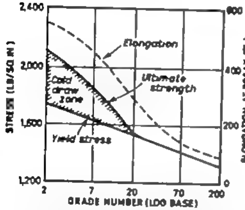


FIG 25 —Effect of grade on mechanical properties. Short time tests (20° C.) Polythene.

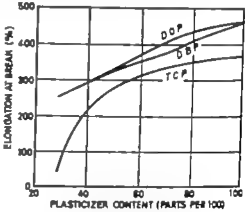


FIG. 26.—Extensibility as a function of plasticizer content. Short time values at 20° C. P v.c. plasticized.

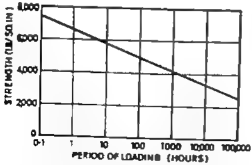


FIG. 27 —Strength as a function of time. Typical trend (20° C.). Perspex.

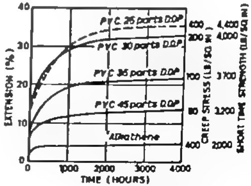


FIG 28.—Tensile creep at 20° C. P v.c. and polythene.

TABLE I

The table of properties must be used with caution. The reasons for this are given in the General Introduction, which should be read before using the table.

Property (23° C and 50% R.H. unless otherwise stated)	Unit	Polythene	P.V.C. Unplasticized	P.V.C. Plasticized	Polymethyl methacrylate	Polystyrene	Nylon	P.T.F.E.
Class		Thermoplastic						
Group		—	Vinyl	Vinyl	Acrylate	Styrol	Polyamide[a]	—
Specific gravity	—	0.92	1.35–1.55	1.25–1.35	1.19	0.98–1.11	1.09–1.14	2.1–2.3
Specific volume	cu. in./lb.	30.1	17.8–20.5	20.5–22.2	23.2	24.8–28.1	24.2–25.5	12.1–13.2
Tensile strength	10^3 lb./sq. in.	1.5–1.8	8–9	1.5–3.5	6–10	3.5–12	7–10.9[a]	1.8
Elongation at fracture		50–400	Up to 100[c]	200–400	2–10	1–30	90–100[f]	310
Modulus of elasticity in tension	10^5 lb./sq. in.	0.19	5	—	3.5–5.0	1.8–6.0	2.6–4.0	0.58
Compression strength	10^3 lb./sq. in.	—	—	—	11–18	4.8–16	7.2–13	1.7
Impact strength (Izod, ½ in. × ½ in. notched bar)	ft. lb. per inch of notch	~16	0.4–0.75[k]	—	0.4–0.5	0.25–11	1	3–4.5
Flexibility: Thin sections	—	Flexible	Flexible	Flexible	Rigid[m]	Rigid[m]	Flexible	Flexible
Flexibility: Massive sections	—	Rigid	Rigid	Flexible	Rigid	Rigid	Rigid	Rigid
Design criterion	—	Strain	Stress	Strain	Stress	Stress	Indeterminate	Indeterminate
Maximum continuous safe working stress (20° C.)	lb./sq. in.	200–350[g]	700	100[f]	1,000	—	—	—
Thermal conductivity	10^{-4} cal./sq. cm./sec./°C./cm.	8	3.5–4	3–4	4–6	1.33	5.2–5.8	6
Specific heat	cal./°C./gm.	0.55	0.24[c]	0.3–0.5	0.35	0.32–0.35	0.4	0.25
Coefficient of linear expansion	10^{-5}/°C.	16–18	8[c]	10[c]	9	3.4–21	10–15	10
Limiting temperature	°C.	100	55–70	65–80	60–95	60–95	130–190	260
Volume resistivity	ohm-cm.	> 10^{16}	10^{14}	10^{11}–10^{14}	10	10^{16}–10^{19}	10[illegible]	10^{15}
Dielectric strength	volts/0.001 in.	460[f]	700–1,300[m]	800–1,000[m]	450–900	300–700	380–470	480
Dielectric constant (1,000 cycles)	—	2.3	3.0–5.0	4.0–5.0	3.0–3.5	2.45–4.5	4.0–4.5	2.0
Power factor (tan δ at 1,000 cycles)	—	< 0.0005	0.02–0.16	0.09–0.16	0.03–0.06	0.0001–0.02	0.02–0.04	0.000
Water absorption (24 hours. Specimen ⅛ in. thick)		< 0.01	0.07–0.08	0.4–0.65	0.3–0.4	0.03–0.[illegible]	0.4–1.5	0
Burning rate	—	Slow	Self-extinguishing	Slow to self-extinguishing	Slow	Slow	Self extinguishing	Nil
Clarity: Film	—	Transparent	Transparent	Transparent	—	—	Transparent	Translucent
Clarity: Thin sections	—	Translucent	Translucent	Transparent	Transparent	Transparent	Translucent	Opaque
Clarity: Massive sections	—	Opaque	Opaque	Translucent	Transparent	Transparent	Opaque	Opaque
Refractive index number	—	1.51	—	—	1.49–1.50	1.56–1.66	1.53	1.35
Colour possibilities	—	Unlimited	Unlimited	Unlimited	Unlimited	Unlimited	Unlimited	Limited[p]

TABLE I—continued

Property (21° C. and 50% R.H. unless otherwise stated)	Units	Cellulosics	Casein Plastics	P.F	U.F	M.F	Polyester Resin	Epoxy Resin
Class		Thermo-plastic	Indeter-minate	Thermosetting				
Group		—	—	Phenoplast	Aminoplast		—	—
Specific gravity	—	1·09–1·4	1·35	1·3–2	1·47–1·52	1·45–2	1·1–1·46	1·11–1·23
Specific volume	cu. in./lb.	19·8–25·5	20·5	13·8–21·3	18·2–18·8	13·8–19·1	19–25·2	22·5–24·9
Tensile strength	10^3 lb./sq. in.	1·9–8·5	10	3·3–9[c]	6–13	5–13	5–6[d]	12
Elongation at fracture	%	4–75	2·5	0·13–2	0·5–1	0·3–0·9	+ 5	—
Modulus of elasticity in tension	10^5 lb./sq. in.	0·7–4	5·1–5·7	8–40[g]	15	11–16	3–6·4	4·5
Compressive strength	10^3 lb./sq. in.	7·5–36	27–53	12–36[h]	25–35	25–43	13–27[j]	16
Impact strength (Izod, ½ in. × ½ in. notched bar)	ft. lb. per inch of notch	0·4–7	1	0·24–8	0·25–0·35	0·24–1·4	0·2–0·4	0·5–1·7
Flexibility								
Thin sections	—	Flexible	Rigid	Rigid	Rigid	Rigid	Rigid[m]	Rigid
Massive sections	—	Rigid	Rigid	Rigid	Rigid	Rigid	Rigid	Rigid[n]
Design criterion	—	Indeter-minate	Stress	Stress	Stress	Stress	Stress	Stress
Maximum continuous safe working stress (20° C.)	lb./sq. in.	—	—	—	—	—	—	—
Thermal conductivity	10^{-4} cal./sq. cm./sec./° C./cm.	3·8–8	—	1·16	7–10	6·5–17	4	—
Specific heat	cal./° C./gm.	0·3–0·75	—	0·28–0·4	0·4	—	—	—
Coefficient of linear expansion	10^{-5}/° C.	8–20	4·1–6·8	1·5–4·5[r]	2·7	2–4·5	8–10	6
Limiting temperature	° C.	55–105	[illegible]	120–260	75	100–200	120	150
Volume resistivity	ohm-cm.	10^{10}–10^{14}	—	10^{9}–$>10^{12}$	10^{12}–10^{14}	10^{9}–10^{14}	10^{14}	10^{14}–10^{16}
Dielectric strength	volts/0·001 in.	250–400	400–700	72–460	300–400	130–400	380–500	400
Dielectric constant (1,000 cycles)	—	3·0–7·0	6·5	4·4–9·0	7–7·5	6–9·7	2·8–5·2	3·67
Power factor (tan δ at 1,000 cycles)	—	0·002–0·06	0·05[s]	0·007–0·4	0·025–0·040	0·013–0·070	0·003–0·025	0·0024
Water absorption (24 hours. Specimen ⅛ in. thick)	%	0·8–6·5	7–14	0·01–1·75	0·4–0·8	0·08–0·8	0·15–0·6	0·14
Burning rate	—	Self extinguishing to very high[v]	Very low	Nil to very low	Very low	Nil	Self-extinguishing to slow	Slow
Clarity:								
Film	—	Transparent	—	—	—	—	—	—
Thin sections	—	Transparent	Translucent	Opaque[e]	Trans-lucent[e]	Translucent	Transparent	Transparent
Massive sections	—	Transparent	Opaque	Opaque[e]	Opaque[e]	Opaque	Translucent	Translucent
Refractive index number	—	1·46–1·51	—	1·58–1·66[r]	1·54–1·56[r]	—	1·53–1·[illegible]	—
Colour possibilities	—	Unlimited	Unlimited	Dark colours only[e]	Unlimited	Unlimited	Unlimited	Wide choice

(a) Nylon — the generic name for the polyamide group of plastics.
(b) Tensile strength of drawn nylon monofilament can exceed 50,000 lb./sq. in.
(c) Tensile strength of P.F. laminates in the direction of the laminations can exceed 40,000 lb./sq. in.
(d) Tensile strength of glass-reinforced polyester resins can exceed 100,000 lb./sq. in.
(e) Data not given in original chart. Figures shown in the table apply to equivalent material in this country tested at 20° C.
(f) Elongation at fracture of drawn nylon monofilament may be less than 30%.
(g) Cast P.F. resin has a modulus of elasticity of about 4·5 × 10^5 lb./sq. in.
(h) Compressive strength of P.F. laminates at right angles to laminations can exceed 45,000 lb./sq. in.
(m) The material is not produced in sufficiently thin sections to be flexible.
(n) Some compounds can be flexible.
(p) Working stress depends on the degree of creep that can be tolerated.
(q) Working stress is very dependent on plasticizer content and on the degree of creep that can be tolerated, but all flexible plastics have high creep rates at small fractions of the short time strength.
(r) Cast P.F. has a coefficient of linear expansion of approximately 9 × 10^{-5}/° C.
(s) The figure shown is about half the dielectric strength of Alkathene.
(t) The dielectric strength of p[illegible] is normally about half the figure shown.
(v) Cellulose nitrate (celluloid) is violently inflammable.

TABLE II

CHEMICAL RESISTANCE.

Polymer	Solvent		Exposure	Oxidation	Water	Acids	Alkali	Aqueous	Halogen
	Organic	Inorganic							
Polythene	Selective	Resistant	Protected by carbon black	Protected by antioxidant	Resistant	Resistant	Resistant	Resistant	Mostly resistant
Unplasticized p.v.c.	Selective	Resistant	Darkening only	Resistant	Affected by hot water	Resistant	Resistant	Resistant	Mostly resistant
Plasticized p.v.c.	Resistance affected by comparison with unplasticized p.v.c. all along the line by plasticizers; although by selection excellent service can be obtained.								
Nylon	Resists most	Resists most	Some yellowing	Resistant	Absorbs with temporary loss of some strength	Attacked	Resistant	Resistant	Attacked
Perspex	Attacked	Resists	Resists	Resists	Unaffected	Mostly resistant	Resistant	Resistant	Slight attack
Polystyrene	Attacked	Resists	Attacked	Attacked	Resists	Resists	Resists	Resistant	—
P.T.F.E.	Resists	Resists	Resists	Resists	Resists	Resists	Attacked by molten alkali metals	—	Slight attack
Celluloses	Attacked by most	Attacked by many	Attacked	Attacked	Attacked	Attacked	Attacked	Resistant	—
P.F. moulding and resins laminated	Mostly resistant	Resistant	Darkens. Can be pigment protected	Attacked	Good resistance	Attacked by strong acids	Strong alkali attack	Resistant	Attacked
U.P.	Mostly resistant	Resistant	Pigment protects	Attacked	Good resistance	Attacked by strong acids	Weak ones do not attack	Resistant	Attacked
Polyester	Selective	Resistant	Pigment protects	Fairly resistant	Good resistance	Resists weak acids	Resists weak alkali	Resistant	Fairly resistant
Epoxy resins	Fairly resistant	Resistant	Pigment protects	Fairly resistant	Good resistance	Resists	Resists	Resistant	Fairly resistant
Silicones	Swelling only	Resistant	Resists	Resists	Resistant	Mostly resists	Resists	Resists	Attacked
Polyurethane	Mostly resistant	Mostly resistant	Yellows	Resists	Resistant	Resistant	Mostly resists	Resists	Slight attack

Attacked by oxidising acids at high concentration.
Surface attacked by some.
Some swelling.
Superficial attack by potassium permanganate and some other concentrated salts.
Phenol is amongst successful assailants.
With some useful exceptions.
Care must be taken when cutting laminates to see that the fabric filler is not open.

It will be noticed that the coefficient of thermal expansion is much larger is the case with metals and this difference will have to be accommodated whe two are used in conjunction

Chemical properties

Plastics are, as a class, extremely resistant to inorganic media, but are sen to attack in particular cases by organic materials to a greater degree than is with metals

They are normally far more resistant to attack than most natural fib materials and rubber but like them they suffer weakening by the photocher action of strong sunlight, unless protected by dense pigments or other such m Water has some effect on plastics, although relatively little

It must be emphasized that plastics may slowly absorb chemical compo if stored for long periods in antiseptics (Fishburn, 1955) and this hazard will to be checked individually although Table II will provide a rough guide in cases.

WORKING WITH PLASTICS

The plastics fabrication industry may rather like the metal working indust be thought of as operating in two successive stages. Sometimes combined polymerization, as with Perspex, the first stage delivers semi finished mate such as large thick blocks, thinner sheet film or bar and rod stock. The turn form the raw stock of the finishing stages. The three main processes are clo paralleled in metal working, to which in fact they owe their origins

Plastics	*Metal working*
Moulding	Die casting
Extrusion	Extrusion
Calendering	Rolling

Moulding

It is usual in plastics moulding to produce completely finished goods in operation, which is rarely possible with metals which usually cannot be for with the necessary precision and need to be machined to size or have screw thre made.

In plastic moulding operations the material can be placed in the mould, wh is then heated and the material compressed, the more usual system for ther setting types Thermoplastics can also be fed to a heating chamber and for into the mould under pressure, giving a faster operation this is called inject moulding.

All types of moulding machine used by the specialists in this work are becom larger and more complex as the search continues for precision economy increasing size of article These machines are not required by those who need make only a few mouldings very simple and cheap machines are available hand operation Mouldings can also be made from the cold-setting therr setting resins and from others by using special hardeners and catalysts in sim

plaster or wood moulds without mechanical equipment Finished shapes can also be made by these means with fabric reinforced resins and the necessary techniques are not too difficult to acquire

Extrusion

Extrusion simply means forcing material in a molten state through suitable orifices to give the required shape. Copper steel and other metal tubes are made this way in plastics extrusion forms a basis for making a myriad of sections from sheet to small diameter tubing. This process is versatile because plastics are easily melted and made to take up the final shape, whereas the amount of deformation metal will stand in forming is much more limited Here again standard machines are quite complex although some simple extrusions may be got by forcing hot material through a die by a hand-operated ram Adequate results will normally be better obtained by a specialist fabricator

Calendering

A calender consists of accurately made rolls which can be heated, and between which heated plastic is forced to give sheet or film of very accurate thickness This sheet is drawn off allowed to cool and either cut to length or rolled if thin enough.

Subsidiary operations

Subsidiary operations are numerous amongst the most interesting is the shaping of thermoplastics. This is done by heating to softening point—which usually lies low enough to allow heating in boiling water or in very simple ovens.

Rod for example, can be manipulated to shape or sheet may be transferred to a prepared mould This may consist of two simple wooden parts which squeeze the plastic between them, or the sheet may be clamped and either blown by air pressure or sucked by vacuum against the mould. The material is then allowed to cool when it will retain its shape unless it is again heated to its softening point, when it will revert to its original shape. Plastics technicians call this phenomenon " plastic " or molecular " memory

Thermoplastics can usually be welded by heating the two mating surfaces and pressing them together till cold. This is frequently done with films and tubing and is called heat sealing. Another method is to fill the space between them by melting a welding rod made from the same material This is exactly akin to metal welding with a gas flame

Special electric methods are also used for heat sealing. Special glues and solvents are available for sticking both thermoplastics and thermostats to themselves and to other materials such as metal and glass

Some thermoplastics can be dissolved in a solvent and used to make film or for coating articles by dipping them in the solution This is frequently done with polythene and nylon to give chemical protection Foams pastes and gels can be made by adding suitable agents to the polymer and moulded to shape

SUMMARY

This chapter presents a general review of plastics and contains information normally available in literature confined to plastics, to which the reader is referred for a more detailed and exhaustive treatment.

The intention has been to paint simply and on a relatively small canvas, a contemporary picture of a rapidly developing scene which is not confined to plastics in surgical use today and to discuss the nature of the materials in this group with their advantages and limitations and some of the hazards likely to be met in their employment. The physiological compatibility of plastics has deliberately not been discussed, partly because the author considers this subject to lie outside his competence and partly because the experimental evidence in the literature appears too scanty for useful comment. Indeed some of the work appears to have suffered from inadequate control and is misleading.

ACKNOWLEDGEMENTS

I am indebted to many of my colleagues, particularly to T. A. Stanley (from whose work I have borrowed unmercifully) and to Mr. J. T. Scales of the Royal National Orthopaedic Hospital, Stanmore, for much advice and criticism, and to the Directors of the Plastics Division of I.C.I. for permission to publish this work.

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CHAPTER 5

BIOLOGICAL AND MECHANICAL FACTORS IN PROSTHETIC SURGERY

JOHN T SCALES

IN THE last 20 years there has become available a number of plastics and metals with widely differing physical properties The apparent chemical inertness of a number of them has suggested their use for various purposes in surgery A material which is to be implanted in the body must

(1) be chemically inert,
(2) not be physically modified by tissue fluids
(3) not excite an inflammatory or foreign body cell response in the tissues
(4) be non-carcinogenic
(5) not produce a state of allergy or hypersensitivity
(6) be capable of standing up to mechanical strains imposed upon it, as for example friction when placed in a joint
(7) be capable of being fabricated in the form required with reasonable ease and at relatively low cost
(8) be capable of being sterilized.

Before using a material for a particular application a number of factors require consideration in more detail than is apparent from the above list of properties Fig. 29 is an attempt to correlate these interrelated factors, the relative importance of each depending on the purpose of the implant. It is often said that tissues will not tolerate a foreign body and that in the course of time it is always expelled. There is now ample evidence available in the various branches of surgery to disprove this belief

Materials used for implants

Two broad groups of materials are used for implants

Metals

Long experience with metals has demonstrated that the cobalt-chrome alloys, known in America as Vitallium * and in Great Britain as Vinertia † and stainless steel to B S Specification En 58 J (A.I S I 316) have proved most satisfactory providing certain precautions are taken in the manufacture and use of the implants. More recently a commercially pure element—titanium ‡—has become available and experiments suggest that it may be suitable for implant surgery

Plastics synthetic organic materials

Many plastic materials have been used for a variety of purposes, often with unfortunate consequences Although several companies may produce a plastic

* Manufactured by Austenal Labs. Inc. (Surg Division), 224 East 39th Street, New York 16, N Y U S.A.

† Manufactured by Deloro Stellite Ltd., Birmingham, England.

‡ Manufactured by Imperial Chemicals and known as T1.160.

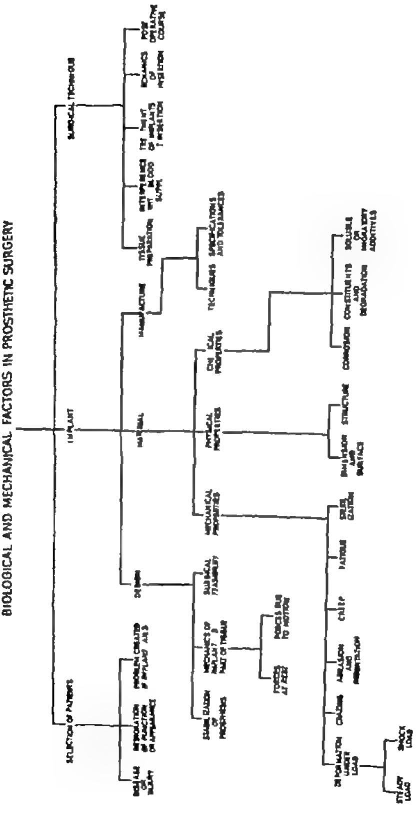

BIOLOGICAL AND MECHANICAL FACTORS IN PROSTHETIC SURGERY
SELECTION OF PATIENTS
IMPLANT
SURGICAL TECHNIQUE
DESIGN
MATERIAL
MANUFACTURE
TISSUE PREPARATION
TECHNIQUES
SPECIFICATIONS AND TOLERANCES
SURGICAL FEASIBILITY
FORCES AT REST
FORCES DUE TO MOTION
MECHANICAL PROPERTIES
PHYSICAL PROPERTIES
CHEMICAL PROPERTIES
CORROSION
CONSTITUENTS AND DEGRADATION
STRUCTURE
FATIGUE
CREEP
DEFORMATION UNDER LOAD
STEADY LOAD
SHOCK LOAD

Fig. 29

F 2

with the same generic name, its composition may differ with each manufacturer A variety of chemical agents or additives are used in the course of manufacture of a synthetic material, for example catalysts plasticizers, dyes pigments, fillers and stabilizers These materials are added to aid manufacture, to modify physical properties, to tint or colour the material, to lower the cost or to retard degradation of the polymer Many commercially available plastics are therefore of an exceedingly complex nature and if possible a qualitative analysis should be obtained from the manufacturer before they are used in the animal or in man. Sometimes the manufacturer is reluctant to give the complete formulation of the products, but without this information experimental work is of little value To use, for example a synthetic fabric which has been purchased from a draper s shop or cut from the tail of a shirt for a vascular prosthesis is wholly indefensible—reports of work with material which has been procured in this way have appeared in the literature There is often considerable doubt as to the composition of the fabric and the fact that nearly all fabrics are contaminated with a variety of spinning and weaving agents is ignored.

An implant is a therapeutic agent and should not be used in man until laboratory investigation and animal experiments establish that the final experiment in man has a reasonable chance of success

IMPLANT DESIGN

Stabilization of prosthesis

Many implants are intended to remain in the tissues for the remainder of the patient s life They are required to restore function for example, the conduction of fluids as in the replacement of a portion of a vessel, to replace part of a bone or joint surface or to occupy space following the removal of tissue as in pulmonary plombage Whatever their purpose these implants must be stabilized and incorporated in the tissues. Initially the implant may be attached to the tissues by mechanical means—by sutures in vascular grafts, by pins or nuts and bolts as with orthopaedic prostheses—or be placed free in a cavity and be supported by the tissues as is the case with a plomb None of these procedures is likely to succeed, however unless the tissues are able to invade the structure of the implant.

In vascular surgery the primary function of the implant is to conduct fluid its secondary function is to act as a temporary scaffolding to enable vascular fibrous tissue to form a new tube On this foundation endothelium is able to migrate from the normal vessel at either end of the implant. A non porous implant will usually fail at its junction with the vessel or clotting will occur within the lumen of the tube

The replacement of portions of the bony skeleton necessitates the union of the implant with the remaining bone by means of nuts, plates and bolts or intramedullary pins. All bones transmit forces of considerable magnitude and permanent stabilization of the implant by these means is likely to fail in the course of time as a result of either material failure of the connecting links or failure of the patient s bone owing to high stress concentrations at the points of contact with the implant.

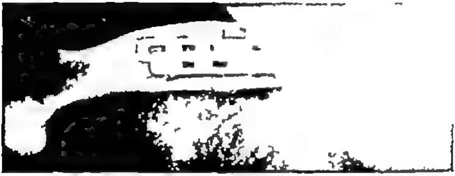
If a pellet or block of an inert plastic or metal, 2 millimetres by 5 millimetres is implanted in muscle it becomes surrounded by a thin, non-adherent fibrous tissue

FIG 30.—Tissue reaction induced by implantation of a pellet of 18/8/1 stainless steel 730 days previously in the anterior abdominal wall of a guinea-pig. *Capsule* Compact fibrous tissue not adherent to implant. Inflammatory and giant cells—nil. Vascular reaction—nil. Composition chromium 18%, nickel 8%, carbon 0·12%, manganese 0·30%, silicon 0·6%. (× 100). (*By courtesy of the Honorary Editors Proceedings of the Royal Society of Medicine*)

FIG 31.—Tissue reaction induced by the implantation 289 days previously of a multifilament polyvinyl chloride thread in the anterior abdominal wall of a guinea-pig. *Capsule* compact fibrous tissue with concentration of nuclei adjacent to implant. The fibrous tissue has infiltrated between the filaments of the thread. There is no tissue fluid space. Inflammatory and giant cells—nil. Vascular reaction—nil. (× 50.) (*By courtesy of the Honorary Editors Proceedings of the Royal Society of Medicine*)

envelope (Fig. 30) There is no increased vascularity in the surrounding tissues. Foreign body giant cells and chronic inflammatory cells are not found The fibrous tissue capsule in the course of time becomes hyaline in nature the cells being flattened and arranged parallel to the surface of the implant. With non-wettable materials or those which have a very low fluid uptake such as polymethyl methacrylate or polythene the capsule is separated from the implant by a small tissue fluid space In bone the implant is surrounded by a layer of fibrous tissue (one to three cells in thickness) without an apparent tissue fluid space If movement

(a)



(b)

FIG. 32.—Mid-shaft replacement in the femur of a goat by a polyester (Marco 61 C) distance piece. Union of the upper and lower portions of the femur by means of slotted plates and nuts and bolts. (a) Twenty-two days after operation. (b) three years after operation. The distance piece is outlined by new bone. Continuity of the femur has been re-established.

of the implant occurs, this fibrous tissue layer becomes increased in thickness When filamentous or porous materials are implanted in muscle they become surrounded by a somewhat thicker fibrous tissue capsule which penetrates the interstices of the implant and makes its removal from the tissues exceedingly difficult if not impossible (Fig. 31) This ingrowth of fibrous tissue anchors the implant. In contrast a smooth implant may be moved around and even extruded by muscle action

Grindlay and Clagett (1949) reported on the use of a sponge of formalinized polyvinyl alcohol (Ivalon) in the pleural cavity of dogs following pneumonectomy They found that both the mediastinal and diaphragmatic surfaces of the sponge were covered by a layer of avascular collagenous fibrous tissue and pleural

membrane The sponge was not adherent to the wall of the thorax. The open spaces within the sponge were lined by a single layer of cells which resembled vascular endothelium Grindlay and Waugh (1951) carried out further experiments with the same material implanted in various situations in the dog for up to 2 years There was no evidence of inflammatory reaction the capsule consisting of bundles of collagen fibres which merged with similar tissue in the interstices of the sponge In the course of time the sponge lost its resilience and had the properties of a block

(a) (b)

FIG. 33 —Replacement of upper half of femur of the goat by an acrylic prosthesis. (a) Eight months after operation. The remnants of bone grafts can be seen on either side of the plates. There is considerable new bone formation around the shaft. (b) Eighteen months after operation. Bone grafts have disappeared and there is a well-formed involucrum around the prosthesis.

of fibrous tissue Polyvinyl alcohol is a water wettable material and it may be that the close association of the fibrous tissue with the sponge is dependent on this property Grindlay has also reported on the use of polyvinyl alcohol sponge to reinforce the wall of aneurysms, with apparent success.

Struthers (1955) reported on the use of polyvinyl alcohol sponge in combination with autogenous bone implanted in the periosteal bed of ribs and in the rectus abdominis muscle. From his experiments he arrived at the following conclusions

(1) Polyvinyl alcohol sponge alone or with transplants of autogenous bone was

tolerated by skeletal tissues for at least 20 weeks without macroscopic or microscopic evidence of a foreign body reaction.

(2) New bone will grow around and within polyvinyl alcohol sponge from skeletal tissues within 4 weeks but does not completely infiltrate the sponge up to 20 weeks The ingrowth of bone occurred mainly from adjacent cancellous bone surfaces but was increased by the addition of chips or smaller particles of autogenous bone to the sponge.

When a segment of the femur of the goat is replaced by a distance piece made of a suitable plastic material, new bone will form in close apposition to bridge across and surround the implant, restoring the continuity of the bone (Fig. 32*a* and *b*) If the upper half of the femur of the goat is replaced by an acrylic prosthesis with bone grafts around the implant an involucrum is formed (Fig. 33*a* and *b*)

As a result of this work and that reported with polyvinyl alcohol sponge implants, experiments are in progress using hollow perforated cobalt-chrome implants

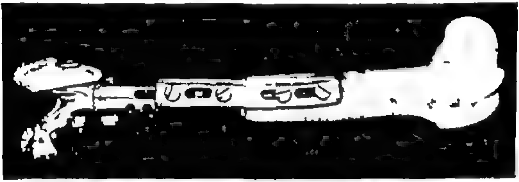


FIG 34.—Perforated tubular cobalt-chrome (Vinertia) prosthesis.

(Fig 34) around and within which homogeneous bone is packed It may be that stability of the implant can be achieved by the formation of new bone within and around the implant, the plates joining the implant to the bone acting only as temporary stabilizing members. Even if bone is not formed fibrous tissue formation *should allow the muscles to gain a mechanical attachment to the implant.*

Mechanics of implant as part of the tissues

Implants are required either to restore physiological function or for cosmetic reasons Whatever their purpose, they will be affected by forces developed within the body by muscle action and by external forces, for example gravity The magnitude and distribution of the principal forces acting in the tissues in which the implant is to be used must be established both at rest and in motion. The operative procedure in itself may alter the normal function of the tissues to such an extent that the implant will be subject to the action of forces of a higher order than normally The implant may be required to withstand the action of intermittent or continuous forces for periods varying from hours to years. The distribution of the forces within the implant has also to be considered. Analysis of

these forces and their effects on the implant are a facet of biomechanics (Chapter 6) which is "that science that investigates the effect of internal and external forces on human and animal bodies in movement and at rest" (Contini and Drilles, 1954) Forces acting on the body while it is at rest relative to its immediate surroundings are known as static forces When relative movement takes place dynamic forces of acceleration and retardation have also to be considered Static and dynamic forces can be resolved into three simple components

(1) Tensile forces which tend to pull the tissues or implant apart.
(2) Compression forces which tend to push the tissues or implant together
(3) Shearing forces which tend to make one part of the tissues or implant slide over the other

The application of a force to an implant can both (*a*) stress the implant that is cause an intermolecular resistance within the material to the force

It is measured as the force/unit area and is expressed in grammes/sq cm or lb /sq in (*b*) strain the implant causing a temporary or permanent change in its linear measurements that is a change in length per unit of length.

Some implants are required to withstand a complex system of forces, as for instance when a part of the skeleton is replaced The design of the implant should be such that high local stress concentrations are not produced either in the implant or in the tissues.

E. J Haboush (1952) has shown that the pressures developed locally in the bone of the lateral cortex of the femur around a nail or pin used in the treatment of a fracture of the neck of the femur can be 60 000 lb /sq in. With such high local pressures necrosis absorption or fracture of the bone may occur The highest compressive strength for the femur quoted by Evans (1957) is 30 150 lb /sq in (Calabrisi and Smith, 1951)

When an implant is to form part of a joint the articulating surfaces should be complementary with the remaining portion of the joint If this is not achieved then the load per unit area to which the tissue surface of the joint is exposed will be considerably greater than that which it has been carrying previously This can only result in considerable damage to the articular cartilage The lubrication of the two surfaces also presents a problem whilst synovial fluid is a satisfactory lubricant for a resilient cartilage to cartilage bearing, it is most unlikely to be a suitable lubricant for a metal or plastic to cartilage bearing. There is no doubt that future progress in arthroplasty lies in the replacement of both joint surfaces by implants Bone will withstand forces of considerable magnitude providing that their direction of application and distribution approximates closely to normal. Many failures of prostheses in the past can be attributed to a lack of appreciation of the magnitude of the forces to which the prosthesis is ultimately exposed

The majority of the work on forces developed in the tissues has been concerned with problems of locomotion (Evans, 1957 Steindler 1955 Klopsteg and Wilson, 1954)

Schenk (1957) has pointed out that the haemodynamic alterations following the replacement of blood vessels by prostheses has largely been ignored

It has been found that the pulse pressure in the dog and man increases from the aortic arch to the smallest arterial channel and that this increase can be as much as 100 per cent This is, of course, the converse of what has been taught

up till now It has also been found that cloth prostheses interfere with the normal pulse progression while homografts have little effect up to 1 year after implantation. Whether the elasticity of the prosthesis can be adjusted to overcome this disadvantage poses an interesting problem As with plombs, the pore size of the structure will determine to some extent the long term mechanical properties of the implant, since massive invasion of the implant by non-elastic fibrous tissue will result in a loss of elasticity of the artificial vessel If elasticity of the vessel is achieved the problem of fatigue failure of the implant will arise (*see* below)

Surgical feasibility

Before proceeding with the manufacture of implants, it is advisable to make a rough model and see whether it can be inserted in the tissues of a cadaver and if so whether the incision can be closed with the implant *in situ* without undue tension of the surrounding tissues A complex design is often difficult to insert and necessitates a more extensive operative procedure than would be necessary for the insertion of a simpler type of prosthesis. The number of components of an implant should be kept to a minimum. This applies particularly to some of the larger orthopaedic implants What may seem a highly desirable method of fixation of the prosthesis to the tissues may be found to be technically exceedingly difficult because of lack of space in which to work or because special tools are required.

The skin over subcutaneous implants is always likely to break down as a result of interference with its blood supply Skull plates, for example, should be liberally provided with ¼ inch or $\frac{1}{16}$ inch holes to allow vessels to grow through and supply the tissues over the plate. Subcutaneous joint replacements should always be made smaller than the joint they are replacing. To prevent necrosis of the subcutaneous tissue and skin all edges should have as great a radius as possible since this minimizes local stretching of the skin and pressure occlusion of the blood vessels during movement If breakdown of the skin occurs over an implant, it is almost impossible to close the defect with a skin graft. When implants are buried deeply in the tissues relatively sharp edges appear to produce no undesirable effects The attachment of muscles and tendons to an implant is often difficult to achieve There should be sufficient holes provided in the implant, without unduly diminishing its strength, to allow the muscle groups and tendons to be brought into apposition with the implant so that they can gain attachment to the fibrous tissue capsule which always forms around implants. The holes provided must if possible be large enough to pull portions of muscle through which can then be sewn back on themselves The muscle tissue may in time be replaced by fibrous tissue or it may necrose nevertheless fibrous tissue attachment to the capsule results It is not advisable to devise a surgical technique which necessitates a two-stage operation, since the risk of infection is greatly increased. Implants should be made to the correct dimensions or require only minor alteration at operation Plastic materials are, of course, very much easier to manipulate than metals

When the implant is ready for clinical trial, it is worthwhile to carry out the " operation on a cadaver A " trial run " enables the steps of the operation to be worked out and written down The detailing of individual steps proves of inestimable benefit to (1) the surgeon and his assistants (2) the anaesthetist, who

knows what to anticipate (3) the nursing staff (4) the photographer who knows what he is to photograph and (5) for record purposes.

IMPLANT MATERIAL

Mechanical properties

Deformation under load

Since many implants are used as load bearing members the same factors as obtain in other critically designed structures must be considered The most important of these factors is the stress which is developed in the material as a result of the applied load In all structural engineering applications it is essential to ensure that the working stresses in an active component fall within the elastic range, that is in that range of stress in which permanent deformation is not produced as a result of applying and removing the load In some materials when the working stresses exceed the upper limit of this range—the elastic limit—the material will be permanently or plastically deformed and repeated applications of this load will cause progressive deformation, which will result finally in failure

In other materials this plasticity does not occur to the same extent and the point at which the material breaks approximates to the elastic limit. This is characteristic of brittleness

In the simple estimation of stress in a structure the load which is supported is divided by the area of cross-section considered, the quotient being expressed usually in pounds per square inch. In practice, however this may not be the actual magnitude of the stress primarily responsible for failure If the structural member has some form of surface irregularity such as a notch or scratch the stress in the immediate vicinity of the defect can be considerably increased These " stress-raisers " as they are sometimes called, can be responsible for the propagation of cracks and the precipitation of structural fatigue This effect is particularly significant in brittle materials and is employed usefully for cleanly breaking a prism of glass along a diamond scratch. If the scratch were not there, the application of the same load would not develop local stresses sufficient to break the glass.

Although it is difficult to obtain accurate knowledge of the stresses which would be developed in a load bearing implant it can be stated with certainty that the load, and therefore the stress, would vary with time and, on occasions this variation could be markedly abrupt An abrupt change of load would constitute an impact and under these conditions the stresses can increase momentarily to very high values Stresses of this kind will be developed when bodily motion is suddenly arrested as for example when stepping "heavily" from a kerb Clearly the more resilient the material of the implant, the lower will be the stress developed in a given impact condition, but taken to an absurd limit this prescribes the use of a material which would be too flexible for the more normal loading conditions The difficulty of designing for shock loading is further increased by the complexities introduced by the method of fixing an implant. In some cases this factor may be more important from the structural point of view than the relevant physical properties of the material used

It is evident even from this short discussion that the structural design of surgical implants presents an intractable theoretical problem Since a solution must be found it is necessary to invoke a more practical approach, aided where possible

by an appreciation of the significance of each of the relevant physical properties. To this end it is essential to obtain more basic information on the materials used in surgery and to study in more detail the structural performance of implants.

The ultimate experiment will always consist of observation of the performance of implants in their appropriate environment, but physical laboratory techniques can undoubtedly reduce both the margin of error and the time consumed in relying only on this method of experiment.

Crazing

Polymethyl methacrylate, polystyrene, cellulose acetate cellulose nitrate, polyvinyl chloride, phenolic resins and polythene are liable to crazing. This has been defined by Simonds, Ellis and Bigelow (1943) as fine cracks which may extend in a network over or under the surface of or throughout the plastic. Crazing appears to be due to the action of solvents, to the presence of monomer

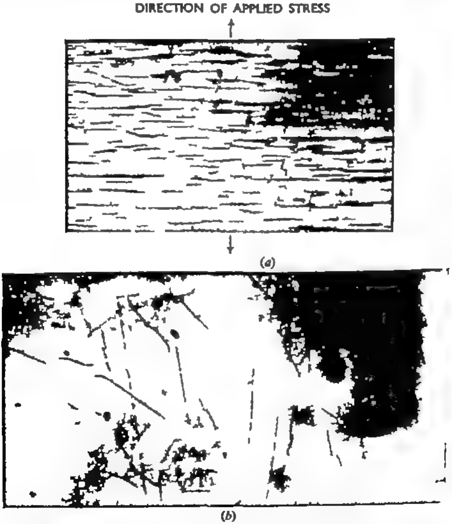


FIG 35.—(*a*) Polymethyl methacrylate crazing under stress (*b*) early stage of solvent crazing of polymethyl methacrylate. Viewed by transmitted light. (× 35) (*By courtesy of the Controller H.M.S.O.*)

which is itself a solvent for the polymer or to mechanical stressing The action of solvents and mechanical stressing together will bring about crazing more rapidly Russell (1948) has studied the phenomenon in *polymethyl methacrylate* He has shown that when tensile stresses are applied to polymethyl methacrylate a characteristic pattern of crazing is seen (Fig. 35*a*) The cracks are orientated at right angles to the direction of the applied stress When solvents are the cause of crazing, a crazy pavement pattern is produced (Fig. 35*b*) In transparent plastics the cracks can usually be seen if the structure is viewed by transmitted light incident ultra violet light shows up the cracks as fine white lines. The small cracks produced in the material can result in a reduction of the mechanical properties of the implant, since they are areas of potential weakness. Many of the failures of the acrylic Judet hip prosthesis have been found to be due to crazing brought about by solvents used in their manufacture and the forced fitting of metal reinforcing members Stress crazing has been seen on the acetabular surface of Judet hip prostheses. As a result of the complexity of forces acting on the hemispherical implant the pattern resembles solvent crazing. A further cause of crazing is high energy radiation. The dosages used to sterilize plastic implants do not however seem to produce this effect

FIG 36.—Crazing of the articular surface of an acrylic Judet hip prosthesis Time in body 21 months. (× 80) (*By courtesy of the Editor British Medical Journal.*)

Abrasion and indentation

All materials are subject to abrasion to a greater or lesser degree. Abrasion resistance to a large extent depends on the hardness of the material. The hardness of a material is an indication of its resistance to deformation and is related to its tensile strength. The hardness is measured by determining the resistance to indentation by a standard form of indentor using a standard load applied for a constant time The Brinell, the Rockwell and the Vickers Diamond Pyramid methods of test are the most usual ones employed. The values of hardness obtained by these different methods are to some extent related and comparable tables are available* With plastic materials the measurement of hardness presents certain difficulties because of their resilience. Plastic materials in contact with

* *Conversion Factors and Tables Industrial Research Service* Page 501 Published by O T Zimmerman (1955), New Hampshire, U.S.A.

bone are particularly liable to wear Impaction of irregularities of a bony surface into the plastic may occur and with movement fragments are gouged from the surface of the implant. Even stainless steel with a Vickers Diamond hardness number 136 which is considerably higher than that of plastic materials used for implants, can wear when used as a femoral prosthesis in hip arthroplasty Surface wear has not been detected with cobalt-chrome alloys in contact with bone The hardness of these alloys used in surgery lies between 310 and 410 (Vickers hardness number) It is possible to increase the hardness of some materials by various treatments as for example the cold working of stainless steels. However by increasing the hardness above a certain value, there is an increasing tendency for the material to become brittle. Brittleness is the tendency for fracture of a material to occur without appreciable deformation and at a low stress value Besides hardness, the rate of movement of one surface on another the lubrication conditions and the nature of the opposing surface influence the rate and extent of abrasion.

Creep or cold flow

Plastics possess the property of creep or cold flow This is the relaxation of the stressed member resulting in a permanent deformation. It is a time dependent phenomenon and occurs particularly with thermoplastic materials. This problem is met in the case of implants which are continuously subject to pressure by the tissues, such as, for example hollow acrylic plombs and hip cups made of thermoplastic materials.

Fatigue

A material which is long subjected to server straining action or to often repeated moderate straining action deteriorates in strength and will break under loads which it previously sustained with safety This is known as fatigue failure. It appears to be due to molecular change in the material.

An implant such as a nylon cord used for replacement of a tendon or ligament is subject to fatigue, either initially before fibrous tissue has formed around and within the cord or for an indefinite period if the function of the implant is not taken over by new fibrous tissue Laboratory tests suggest that a nylon cord is unsuitable for major tendon and ligament replacements

A knotted loop of nylon cord was found to have a tensile strength of 11 000 grammes A similar loop of nylon which had not been implanted in the tissues was arranged in such a manner that it could be alternately stretched and relaxed 37 times a minute in air at room temperature. By varying the loadings used to stretch the cord the following data were obtained

Load applied % of tensile strength	*Frequency of stressing*	*Number of load applications before cord failed*
80	37/min	10
70	”	54
60	”	353
50	”	3 179
40	”	85 410
30	”	infinite (extrapolated)

These results suggest that where a knotted nylon loop is to be used under conditions of alternating load its working strength is probably less than 30 per cent of its ultimate strength If allowance is then made for the loss of tensile strength resulting from degradation of the polymer in the body the impracticability of replacing ligaments with nylon cords becomes apparent, since the required size of the rope, formed by the cords, to function indefinitely would be such that it could not be used Clinical experience has substantiated these experimental findings Fatigue must be considered in the design of any implant that will be subjected to stress Without considering biological influences for a material to withstand a million or more loadings its working tensile strength can be taken as approximately 25 per cent of its ultimate tensile strength

Sterilization

Implants can be sterilized by either physical or chemical means.

Physical methods of sterilization

Heat.—Boiling is the most satisfactory method of sterilization it is simple, quick and no special apparatus is required. If the softening temperature of the material is below 100° C deformation of the implant will occur Even though the moulding temperature of a resin is above 100° C. an implant moulded from sheet material may tend to distort if it is boiled. If it has been injection moulded or polymerized into the desired form and is strain free it will retain its shape

Implants should be wrapped in gauze and suspended in a container of cold water which is then brought to the boil They should not be sterilized together with instruments, otherwise the weight of the instruments may deform the implant

Vascular replacements made from monofilament, for example polythene, which has been stretched during its manufacture, will shrink unless special precautions are taken. The implant must be sterilized on a former from which it should not be removed until it has reached room temperature. Repeated boiling reduces the flexibility of polythene and appears to embrittle it. Small bore polythene tubes which are used for various catheterization procedures should only be sterilized and used once An implant made from a plastic material should be allowed to cool slowly otherwise considerable residual stress may result on sudden chilling, which will unduly weaken the structure.

Nylon and polyfluorotetraethylene can be autoclaved Some degradation of the nylon polymer does, however occur

Radiation.—Two methods are now available (*a*) electron bombardment by means of an electrostatic generator or linear accelerator and (*b*) gamma radiation using a cobalt 60 source

With the electrostatic generator or linear accelerator the thickness of the implant that can be sterilized can be calculated from its density making allowance for any packaging materials The depth of penetration by the electron is dependent on the energy of the electron Assuming that the material has a density of 1 gramme/cm. cube a thickness of ¼ inch can be penetrated for every million electron volts energy (meV) Using 2 meV a ½ inch thick cross-section can be sterilized, but with increasing density there must be a proportionate reduction in cross-section If the packaged material is turned over and passed through the beam a second time

the thickness that can be sterilized may be increased to ¾ inch. The temperature rise in the material during sterilization is not more than 5° C. Experiments have shown that a dosage of two million rads is required for sterilization While this dosage produces minimal degradation of the polymer which is believed to be of no significance increasing the dosage very much above this level may affect the polymer Slight changes in colour sometimes occur but these usually disappear within 48 hours

The implant should be double packed in heat sealed polythene bags of 1½ to 2 thousandths of an inch in thickness Great care should be exercised in heat sealing and the seals should be examined to make sure there are no pin holes or defects The outer bag should be somewhat larger than the inner one At operation the outer bag is opened and the inner bag containing the implant is removed with sterile forceps

With gamma radiation there is no limit to the size of the implant that may be sterilized The size of the gamma source determines the length of time required for sterilization.

Neither method results in any residual radioactivity in the implant. The advantage of gamma radiation is that metal or glass containers can be used. Radiation methods of sterilization are relatively new and further work on the tissue reaction to materials sterilized by these means is required.

Ultra-violet light—This method is not recommended, although it has been used for polythene and certain polyvinyl chloride films The depth of penetration of the material by the bactericidal part of the ultra violet spectrum is about 1/1000 inch. Changes in the chemical structure of polymers can result.

Chemical methods of sterilization

A number of agents is available It is most important to ensure that the one chosen (*a*) is not absorbed by the plastic and then released at a later date in the tissue with resulting cell damage (*b*) does not attack the material and (*c*) is removed from the implant, particularly if the implant is hydrophylic or of a porous structure It is often exceedingly difficult to wash such implants free of sterilizing agents.

With acrylic implants, immersion for one hour in a 0 2 per cent solution of mercuric oxycyanide followed by several rinsings in sterile distilled water has been found satisfactory Alcohol should not be used. Recently Ridley (1957) has developed a method of sterilizing intraocular acrylic prostheses using 0 1 per cent caustic soda. Before use the lenses are washed in excess 0 5 per cent sodium bicarbonate. The implants are stored in the caustic soda in a sealed polythene container to prevent absorption of carbon dioxide from the atmosphere. A 1 in 1 000 aqueous solution of Zephiran (benzalkonium chloride) or Ceeprin (cetyl pyridinum chloride) for 24 hours has been widely used for polythene implants. The implant should be weighted down in the solution, as the density of polythene is 0 93 Formalin vapour sterilization is not recommended for implants made from synthetic materials.

In sterilizing stainless steel implants, no agent should be used which liberates free chlorine bromine, iodine or fluorine ions. These implants should never come into contact with solutions of iodine. All the halogens are corrosive to stainless steels to a greater or lesser degree.

Physical properties

Dimensions and surface

Plastics such as nylon * polythene † and polymethyl methacrylate‡ when implanted either in block or pellet form provoke a minimal fibrous tissue response in man and in the guinea pig. When abraded as can occur when a prosthesis made of these materials is used in a joint a different tissue reaction occurs. It appears that the degree and type of cellular response is partly dependent on the surface area of the material A one inch cube has a surface area of 6 square inches. If the cube is divided so that the sides of the smaller cubes become 1/1000 inch the surface area exposed amounts to 41⅔ square feet

Leveen and Barberio (1949) implanted finely divided FM 1 nylon, Celluloid Lucite and Teflon, all of which were claimed to be free of plasticizers and colour into the peritoneal cavity of dogs They found the following

Material	Reaction	
	3 days	*70 days*
Celluloid	*Intense fibrinoplastic reaction. The peritoneal cavity contained some serosanguineous exudate. Capillaries were engorged.*	*The acute reaction subsided. Fibroblasts, giant cells and chronic inflammatory cells were found in relation to the Celluloid. The loops of the bowel were held together by dense fibrous tissue adhesions.*
Lucite } Nylon }	Substantially the same as Celluloid.	Same as Celluloid.
Teflon	No acute inflammatory changes no gross evidence of tissue reaction.	Chips surrounded by omentum. No fibroblastic reaction. Some secondary adhesions.

With the exception of Teflon fibroplasia appeared to be progressive. The authors suggested that the physico-chemical nature of the surface is important and they found that with Teflon neither protein nor water was adsorbed by the surface of the material They believed that the wettability of a surface may determine the tissue stimulating properties of a material The authors did not state the size or shape of the particles which they used and it would be difficult to prepare comparable particles from these materials. No tumours developed in the dogs

If a polymer is abraded in the body then any degradation products from the powdered material in a given period of time will be very much greater in amount than from a block of the same material The movement of the particles within the tissues may also have a bearing on the degree of reaction Nylon, polythene and non plasticized polymethyl methacrylate have been used for various reconstructive procedures of the hip joint in man Nylon and polythene are crystalline, while polymethyl methacrylate is amorphous The shape, size and quantity of the particles produced by abrasion differ Polythene, being the softest material abrades into relatively large particles, irregular in outline the majority being 200–300μ in size. In the case of nylon the particles are about 1–10μ, relatively few

* Nylon, grade A.100. Manufactured by Imperial Chemical Industries Ltd.
† Alkathene, grade 2. Manufactured by Imperial Chemical Industries Ltd.
‡ Transpex (unplasticized block). Manufactured by Imperial Chemical Industries Ltd.

being up to 200μ in size Both these materials are refractile and the particles can be seen if the histological preparations are examined by polarized light. Polymethyl methacrylate is non refractile and its detection is exceedingly difficult, since it does not take up the normal histological stains

The histological picture of tissue removed from patients in which nylon grade A.100 Judet prostheses or hip cups have been inserted is characterized by zones of fibrous tissue, histiocytic proliferation and amorphous necrotic material (Fig. 37) The compact fibrous tissue is relatively avascular being penetrated by

FIG 37.—Tissue from hip joint. Some larger fragments of birefringent nylon can be seen mainly in the amorphous areas. Vascular histiocytic tissue surrounds these areas. (Partially crossed polaroids, × 30.) (*By courtesy of the Editor Acta Orthopaedica Scandinavica*)

only a few capillaries, and does not contain any particulate nylon In between the zones of fibrous tissue and amorphous material are vascular septa of loose fibrous tissue concentrations of histiocytes loaded with birefringent material which displaces the nucleus of the cell are seen around and in relation to the vessels (Fig 38) Some of these cells contain lipoid material. Away from the vessels in these areas the histiocytes have poorly staining nuclei and are separated from the fibroblasts by an increasing amount of collagen. As the distance from the vessels increases nuclear material disappears, leaving only aggregates of particulate nylon which shadow the shape and position of the histiocytes (*Fig. 39*). Finally there is dissolution of the collagen and the cell membrane with dispersion of particulate nylon in an amorphous debris (Fig. 40) In the histiocytic and fibrous tissue zones foreign body giant cells are sometimes seen, particularly in relation

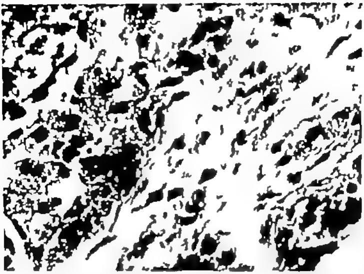


FIG. 38.—Histiocytes loaded with birefringent material in relation to vessels. From the case illustrated in Fig. 37 (× 140.) (*By courtesy of the Editor Acta Orthopaedica Scandinavica.*)

FIG. 39.—Increase in collagen formation with disappearance of nuclei of histiocytes. From the case illustrated in Fig. 37. (× 200.) (*By courtesy of the Editor Acta Orthopaedica Scandinavica.*)

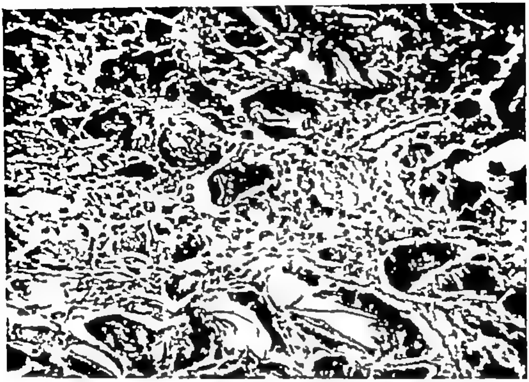
FIG. 40.—Central necrotic area filled with birefringent particulate nylon. From the case illustrated in Fig. 37 (× 200.) (*By courtesy of the Editor Acta Orthopaedica Scandinavica.*)

to larger fragments of nylon. Heck and Chandler (1954) and Levy, Lipscomb and McDonald (1954) have reported similar tissue reactions to nylon hip prostheses. The greater number of giant cells reported by them may be due to the fact that their implants were made from American nylon. It is posible that this polymer differs slightly in chemical and physical properties from the British polymer and therefore the size and shape of particle produced by abrasion may not be comparable

When polythene is abraded in a joint (Newman and Scales 1951), larger

FIG 41.—Condition 114 days after polythene cup arthroplasty Areas of rarefaction in acetabular roof

irregular shaped particles are produced. A female patient aged 53 years suffering from bilateral osteo-arthritis had a right sided polythene cup arthroplasty Nine weeks after operation the hip was painful and after a further 7 weeks there was increased pain with restriction of movement and a radiograph suggested the cup had worn through There was erosion of the acetabular roof (Fig. 41) At operation it was found that the cup was perforated in the weight bearing area and there was a moderate amount of straw-coloured fluid in the joint as well as fibrous tissue about half a centimetre thick lining and invading the roof of the acetabulum. Histological examination of the tissue showed that it contained a considerable number of refractile particles of polythene which were both free in the tissues and contained within giant cells (Fig. 42*a* and *b*) There was a moderate fibroblastic



(a)

(b)

FIG 42.—(a) Giant cells with polythene inclusions. There is a considerable fibrous tissue reaction. From the case illustrated in Fig. 41 (b) the same field as that of (a), viewed under polarized light. (*By courtesy of the Editor Journal of Bone and Joint Surgery*)

(a)

(b)

FIG. 43.—(a) Erosion of the acetabular roof in a patient with an acrylic Judet arthroplasty. (b) fibrous tissue with giant cells in relation to fragments of acrylic resin from worn Judet. From the case illustrated in (a)

response, the fibrous tissue having some sinusoidal like spaces containing blood cells. No lymphocytes were seen

Histological examination of tissue removed from patients in whom wear of acrylic hip prostheses had occurred has shown that the tissue response is essentially one of active fibroblastic proliferation with a few giant cells. The particles of acrylic resin are plate-like and more regular in outline. Lymphocytes are not found. Radiographs of joints in which wear of prostheses has occurred show erosion of subchondral bone with loss of joint outline (Fig. 43*a* and *b*)

The occurrence of malignant tumours in relation to implants of metals and plastics in the rat and mouse has been reported. These tumours have in most cases been fibrosarcomas. In man no malignant tumours have been reported in relation to implants made of plastic materials. Malignant tumours have developed at the site of corroded metallic implants after many years. Siddons and MacArthur (1952) reported 2 cases in which malignant changes occurred around metallic foreign bodies after 32 and 35 years respectively. Penn and Epstein (1953) reported on a case of carcinoma of the skin between the eye and the nose which developed over a shell splinter embedded in the tissues 32 years previously. McDougall (1956) described a case in which a malignant tumour developed in relation to a corroded plate and screws used about 30 years previously for a fracture of the right humerus. He reported that the composition of the plate was 74 per cent iron 18 per cent chromium, 8 per cent nickel and of the screws was 88 per cent iron and 12 per cent chromium. Schinz and Uehlinger (1942) produced sarcomas in rabbits with chromium, cobalt and arsenic implants. Some tumours developed at the site of the implant and others in the lung. The yield was 65 per cent in the rabbits surviving for more than 3 years. Hueper (1952) reported sarcomas in relation to implants of nickel in rats. Heath (1956) found that pure cobalt metal in powdered form produced malignant tumours (sarcomas) in the muscle of the rat. Turner (1942) found that a fibrosarcoma developed at the site of implantation of a phenol formaldehyde (Bakelite) disc 18 millimetres in diameter 1 5 millimetres in thickness, implanted subcutaneously in the Wistar rat. Discs of the resin were implanted subcutaneously into 13 rats, 9 of which lived to 20 months or more. Tumours developed in 4 rats, the first at 18 months. Other workers had established that the constituents of the resin had no carcinogenic activity. Turner found no tumours when squares of the same resin 10 millimetres by 10 millimetres by 1 5 millimetres were implanted subcutaneously into the abdominal wall of 10 male D.B A. strain mice. Oppenheimer, Oppenheimer and Stout (1948) reported that sarcomas occurred in relation to regenerated cellulose film (Cellophane) wrapped around the kidneys of Sherman strain rats to produce hypertension. They followed up this observation by implanting regenerated cellulose film (Visking 5 HS—cellulose sausage casing) into two groups of 55 rats. In one group the left kidney of each rat was wrapped with the film, in the other group a piece of the film 2 to 3 centimetres square was embedded subcutaneously in the anterior abdominal wall, the film being kept flat by catgut sutures passed through the corners of the film. Of the rats, 23 with wrapped kidneys and 42 with subcutaneous implants survived more than 11 months and of these 35 per cent in each group developed sarcomas. In some cases the tumours were transplanted to the fifth generation. Laskin, Robinson and Weinmann (1954), Druckrey and Schmahl (1952), Oppenheimer and his colleagues (1955) and Northdurft (1956)

have found that in the rat or mouse or both malignant changes occur in the capsule surrounding both metallic and polymeric implants. It cannot be too strongly emphasized that no neoplastic changes have been reported in relation to 18/8/Mo (18 per cent chrome, 8 per cent nickel 2 per cent molybdenum) stainless steels, cobalt-chrome implants, or polymeric implants in man

In the Oppenheimers experiments malignant tumours were induced in Wistar and Sherman strain rats and in mice of the Longacre, Paris and C.57 strains by the subcutaneous implantation of small squares or circles of film, approximately 15 millimetres in width, of Cellophane, Dacron, polyethylene, polyvinyl chloride, Celastic, Pliofilm, nylon, polymethyl methacrylate, polystyrene, Saran Ivalon, KEL F Teflon and silk Some of these materials were commercial products and

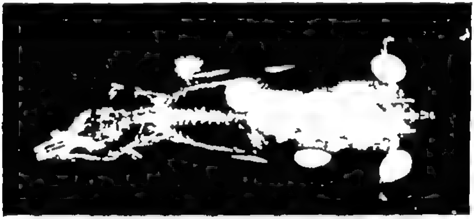


FIG. 44—Radiograph of rat showing 8 silver discs 0 5 millimetre in thickness, 17 millimetres in diameter implanted 15 months previously A tumour has arisen in relation to the right anterior disc. (*By courtesy of Dr H Nothdurft*)

their chemical composition is not stated. The thickness of the film varied from 0·01 millimetre to 0·4 millimetre. They investigated the possibility of breakdown of the polymers by including in certain materials ^{14}C It was found that ^{14}C could be recovered in the urine of rats with labelled polythene after 26 weeks and with labelled polymethyl methacrylate after 54 weeks. When the films were removed urinary radioactivity disappeared

Nothdurft (1956) implanted a variety of materials subcutaneously in the following forms

(1) Non perforated discs, 17 millimetres in diameter (group 1 *see* Table) (Fig. 44)

(2) Perforated discs, 17 millimetres in diameter (group 2, *see Table*), the perforations being carried out by means of a hand-sewing machine

(3) Powders (group 3 *see* Table)

(4) Miscellaneous—rods, balls and bristles

The source of supply and exact chemical composition of the materials used have not been given. The Table shows the incidence of sarcomatous change Only those animals which were alive at the time of development of the first tumour in each

group have been considered in the analysis Wistar rats were used, but it is not stated whether they were pure line strain

TABLE

Material	Group 1 Non-perforated Discs 8 implants per animal		Group 2 Perforated Discs 8 implants per animal		Group 3 Powder 10 implants per animal	
	Total No of rats*	Tumours	Total No of rats*	Tumours	Total No of rats at month 18	Tumours
Gold	77	68	—	—	—	—
Silver	84	65	—	—	—	—
Ivory	69	52	—	—	—	—
Platinum	73	39	—	—	—	—
Polystyrene	47	37	98	40	34	nil
Hydrocellulose (Cellophane)	72	59	61	44	38	1
Polyvinyl Chloride	95	75	76	33	40	nil
Total for all materials	517	395	235	117	112	1

* Refers to the total number of rats alive at the time of development of the first sarcoma.

A number of theories have been advanced in an endeavour to explain the neoplastic activities of these materials Nothdurft believes that it is the physical form of the implant which is the deciding factor and that the chemical nature of the implant is largely unimportant It is impossible to find a common chemical agent in all the different materials which have been cited in the various published reports Thus for chemical agents in implants to be the cause of tumours it must be accepted that there are very many which are carcinogens Their rate of liberation will depend on the dimension of the implant and the solubility of the material With powdered materials it might have been thought that if a chemical carcinogen were involved the tumour incidence would have been increased, but this is not the case. The " cell dosage rate," that is the quantity of the carcinogen being taken up by the cell per unit time may be critical for the development of neoplasia

Both Oppenheimer (Figs. 45 46 and 47*a* and *b*) and Nothdurft (Fig. 48*a* and *b*) have found that the tumours develop in the layer of cells immediately adjacent to the implant Malignant changes are not usually apparent in the capsule for at least a year and in many cases considerably longer (Fig. 49)

With polymer implants the highest incidence of tumours is found in relation to non-perforated discs between 12 and 20 millimetres in diameter Nothdurft (personal communication) believes that with a non perforated disc a relatively *avascular* capsule develops and that in the course of time metabolic changes occur in the cells adjacent to the implant. Powdered implants have a good blood supply and the hyaline changes seen in the fibrocytes adjacent to the non-perforated discs

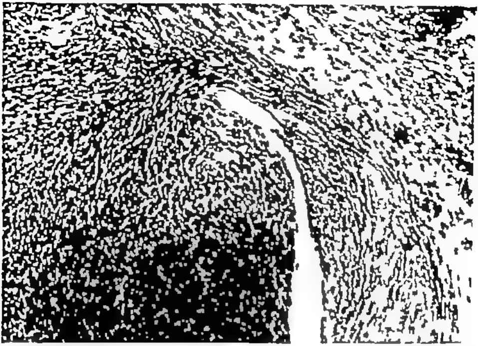


FIG. 45.—Nylon film (512 days). (×100.) Shows end of pocket with fibrosarcoma springing from end and muscle side of pocket and showing continuity with the non-sarcomatous patch of fibroblastic activity on the opposite (skin) side. (*By courtesy of Mrs E. T. Oppenheimer and the Editor of Cancer.*)

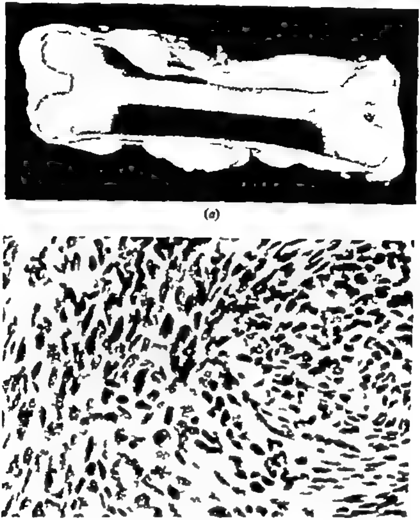
FIG. 46.—Polymethyl methacrylate D (492 days). Fibrosarcoma. Pocket or cleft left by removal of film in a fibrosarcoma induced by polymethyl methacrylate. The tumour cells completely line the cleft which contained the implant. (*By courtesy of Mrs E. T. Oppenheimer.*)

(a)

(b)

FIG 47.—(a) Polystyrene D 400 (309 days) Fibrosarcoma on one wall of pocket with opposite wall inactive. The sarcoma cells are continuous with the inactive part of the pocket wall (upper end) (b) Polystyrene D 400 (309 days) Same as (a) (× 225) (*By courtesy of Mrs E. T Oppenheimer*)

do not occur in the fibrocytes adjacent to the particles. Goldblatt and Cameron (1953) have found that a reduced oxygen tension was a common factor in the production of malignancy in tissue culture experiments *in vitro* Leighton, Kline and Orr (1956) have found that normal human fibroblasts from a 4-day-old infant's foreskin implanted into cellulose sponge matrix tissue culture and subcultured at regular intervals showed malignant changes after 23 months They were not able to confirm their findings by transplantation into man It is suggested that "anaerobiosis could have contributed to the formation of a morphologically malignant variant." The facts here recorded are very mystifying and any explanation of them must be highly speculative.



(a)

(b)

FIG 48.—(a) Silicon rubber buttons, 17 millimetres in diameter (R20 polymethylsiloxan, molecular weight 200,000. Manufactured by Wacker and Company, Munich). Early stage of a capsule sarcoma with tumour nodule formation in the capsule. (× 4.5) (b) Section from the tumour Spindle-celled sarcoma. (× 300) (*By courtesy of Dr H Nothdurft*)

If a non perforated disc of a biologically inert material is implanted in the tissues of the rat, a fibrous tissue capsule develops. If the implant is of a critical size cells in a certain part of the capsule particularly in the layer adjacent to the implant, may have a reduced blood supply Possibly over a prolonged period cellular metobolic processes are disturbed which leads to tumour formation The implant might thus be termed a physical carcinogen since in itself it does not provide a chemical carcinogen The concept that dimension in relation to blood supply is a critical factor might explain why such a variety of inorganic and organic implants can result in tumour formation Some materials however such as cobalt are primary chemical carcinogens in that they are soluble in tissue fluids, pass into the cell and interfere with metabolic processes The " cell dosage rate "

FIG. 49.—Polyethylene C 14 (491 days). Inactive pocket. The fibrous sheath or pocket has very few fibroblasts and no inflammatory reactions or tumour. (*By courtesy of Mrs E. T. Oppenheimer and the Editor of Cancer*)

will be dependent on the dimensions of the implant and thus powdered implants of chemical carcinogens might be expected to be more active than discs of the material. An implant could be both a physical and chemical carcinogen in a particular species of animal if the implant was of the correct dimension and also contained a suitable chemical agent. There is one important aspect of this whole problem, the majority of the work has been confined to the rat although some experiments have been carried out using other species of rodents. It may well be that the reaction of rodents has little bearing on what might occur in other animals, including man although this can be decided in the course of time.

Whether the experimental findings in the mouse and rat are applicable to man can be decided only in the course of time. Plastic materials have been used in man only during the last 18 years and it may be that 30 to 40 years will have to elapse before any tumours develop. The few tumours that have been reported in relation to metallic implants which are alloys and not pure elements indicate the necessity for prolonged observation of patients in whom prostheses have been used.

Structure

Many implants need to be of a porous structure to allow the ingrowth of tissues. However certain areas of the implant, for example an articular surface, may have to be non-porous The most important consideration is that the implant should have adequate mechanical properties to withstand the stresses and strains imposed upon it for prolonged periods. Essentially there are two types of porosity in one the cells are closed and in the other they are open For implants the open cell structure is required. This type of porosity has so far not been achieved with cobalt-chrome or stainless steel implants Plastic materials can be rendered porous by incorporating up to 80 per cent by weight of a suitable water soluble filler The technique of making such materials is complex, since the particles of the filler may become encapsulated by the plastic material. With flexible plastics the septa between the cells can be ruptured by passing the material through calender rolls. The size of pore required between the cells depends on the type of implant but in any case it should not be less than 100μ. It may be an advantage to construct an implant from more than one material in order to employ the properties of each to their best advantage Pangman and Wallace (1955) found that in the treatment of under-developed breasts by " breastplasty " it was preferable to use a two-part implant. The outer coat was of a porous polyvinyl alcohol (Ivalon) while the main mass of the implant was a water impervious sponge. With this type of implant the number of cases in which complications occurred was less than when Ivalon was used on its own. The resilience of the implant was maintained and in the post operative period dead space was smaller and the risk of infection less

Chemical properties

Corrosion

Some elements and alloys, for example cobalt-chrome molybdenum alloys, do not appear to be subject to corrosion under any conditions in the body These materials do not depend for their corrosion resistance on a coherent film of chromium oxide on the surface of the alloy whereas this is essential for resistance in ferrous alloys. In the absence of oxygen the film on ferrous alloys cannot be maintained and the metal is exposed to attack by electrolytes in the environment The most corrosion resistant stainless steel currently available is one that conforms to British Standards specification En 58 J Corrosion of this alloy has been found to occur most commonly where two components are in contact. In these areas the protective chromium oxide film is disrupted. Corrosion may also result at the site of inclusions of oxide scale. Welding of implants is inadvisable since local changes in the structure of the alloy are very liable to occur Stainless steel reinforcing rods embedded in polymethyl methacrylate hip prostheses have corroded. High local stress concentration, relative movement between metal and plastic, and possibly lack of oxygen are the probable causes. When an implant corrodes in the tissues metallic ions are liberated and an inflammatory reaction ensues. Corrosion of metals is dealt with in more detail in Chapter 6

Constituents and degradation

The metallic elements, alloys and plastic materials used in surgery are chosen for their apparent chemical inertness The constituent elements of an alloy or the

simpler units from which a polymer has been formed may however by themselves be chemically reactive Under certain circumstances these reactive constituents may be liberated and cause tissue reactions

The application of methyl methacrylate to the skin of the rabbit or man causes an erythematous reaction Dentures which have been relined with acrylic dough and then placed in the patient s mouth before the resin has cured have provoked an acute inflammatory reaction with the formation of blisters If methyl methacrylate is instilled into the rabbit s eye conjunctivitis results which only slowly disappears. Spealman and his colleagues (1945) found that about a third of the animals studied by the patch test method developed a mild erythema at the site of application of the monomer 10 days later 20 per cent of the animals gave a positive sensitivity reaction However the polymer has been used extensively in the body and no sensitization phenomena have been reported In fact, Blaine and Oliver (1952) and Henricksen Jansen and Krogh Poulson (1952) have used cold-curing polymethyl methacrylate resins in the replacement of bone defects. Their results suggested that the free monomer which was present in the acrylic dough did not produce any permanent tissue damage. Nevertheless, they did not patch test their patients at a later date Henricksen and others found that if the articular cartilages of the femoral heads of young pigs were removed and replaced by acrylic caps attached to the bone by a cold polymerizing cement, at post mortem 2 months later they were firmly fixed to the bone. Woringer (1952) used a cold polymerizing acrylic resin for the repair of cranial defects in animals and found that after 2 years no harmful effects were produced by free monomer or the catalyst used to bring about the cure of the resin. Kramer and McLean (1952) reported that with certain cold-curing acrylic dental filling materials used in unlined cavities in teeth there was an acute inflammatory reaction. They believed, however that the damage caused to the pulp was not of a permanent nature. Nothing is known about the long term effects of traces of monomer which may be liberated by the slow breakdown of an implant due, for example, to abrasion

In an aqueous environment a polymer may degrade. For example when nylon A.100 moulding granules are soaked for a few minutes in distilled water a shift in the *p*H from 6 5 to 7·0 both by indicator and *p*H meter methods, has been noted. After 5 hours refluxing in pyrogen free water a brownish crystalline deposit was obtained. No end point was reached after refluxing with intermittent removal of the extract for a further 40 days. It was found that a cyclic diamide and a dimer of the diamide were being formed. Short term experiments in mice, guinea pigs and man did not demonstrate that these simple compounds had any physiological action (Scales, 1957) However such degradation can result in a lowering of the mechanical properties of the polymer

Soluble or migratory additives

As has been mentioned earlier plastic materials are liable to contain various additives Some of these chemical substances may be water soluble or may migrate from the material over a period of months or years Plastics may pick up various agents from apparatus with which they come into contact during their manufacture. Duncan and Goodwin (1949), following the work of Page (1939) Graef and Page (1940) and Poppe and Oliveira (1946), used a combination of regenerated cellulose film (Dupont Cellophane 300 P U T 71) and polythene film

(Dupont N V 7/14) to produce fibrous obstruction of the ureters and urethra in dogs Animals which had not died for one reason or another within 8 months were sacrificed Duncan and Goodwin found that a marked fibrous tissue reaction had occurred in relation to the materials These results conflicted with the findings of Ingraham Eben and Matson (1947) who had found that polythene produced very little fibrous tissue reaction when implanted in the brain of dogs, while Dupont Cellophane P T which Poppe had found comparatively inert, did in fact, produce a fibrous tissue reaction, as had been found to occur by Duncan and Goodwin in 1949 Yeager and Cowley (1948) realized that there was complete confusion regarding the terminology of the different films which had loosely been called polythene-Cellophane by some authors There also appeared to be a lack of knowledge regarding the methods of manufacture of the films and it was not realized that differences in manufacturing technique might be responsible for the conflicting findings of the different authors. At that time Dupont were using a solvent casting process to manufacture a type of polythene film They were treating the surface on which the film was cast with a stripping agent—dicetyl phosphate —to facilitate the removal of the polythene film from the casting surface It was found that the dicetyl phosphate which had been picked up by the film was present in less than a 1 per cent concentration Polythene can be prepared free from contaminating agents by the " melt extrusion process Polythene and Cellophane (regenerated cellulose) are not chemically related. Cellophane is water wettable, while polythene is not. Types of Cellophane are produced for packaging applications which are coated with a variety of substances including cellulose nitrate, or even polythene, to reduce their water vapour permeability

Yeager and Cowley (1948) endeavoured to exclude the carcinogenic properties of dicetyl phosphate treated polythene by implanting the film into 20 mice. Two cancer susceptible and two cancer resistant strains were used. The animals were observed for 5 months. No tumours occurred, but the period of observation was too short Further experiments were carried out, lasting up to 3 months, with implants in dogs, rabbits and guinea pigs. A marked inflammatory response with fibroblastic proliferation was found. Control experiments with " melt extrusion " polythene film demonstrated that the dicetyl phosphate was the active agent. While for many purposes a non reactive film is useful for others, such as repair of hernias or strengthening the wall of an aneurysm, a material that will produce a fibroblastic response may be useful. Berman and Hull (1952) treated aneurysms with a 2 per cent aqueous solution of sodium dicetyl phosphate. They found that those patients who did not have dissecting aneurysms showed improvement following this treatment. The following description of the preparation of dicetyl phosphate has been given by Dupont and quoted by Berman and Hull (1952) It is

$$3C_{16}H_{33}OH + P_2O_5 \rightarrow (C_{16}H_{33}O)_2\overset{\overset{\displaystyle O}{\|}}{P}{-}OH + C_{16}H_{33}O{-}\overset{\overset{\displaystyle O}{\|}}{P}(OH)_2$$

In a dry 5 litre four-necked flask equipped with a stirrer dropping funnel and thermometer and closed with a calcium chloride drying tube, 213 grammes (1 5 moles) of phosphorus pentoxide is suspended in 1,500 millilitres of dry benzene. Over a period of about 3 hours a solution of 1 094 grammes (4 5 moles) of cetyl alcohol in 2,000 millilitres of dry benzene is added dropwise at room temperature. During the addition

the temperature rises to about 40 degrees C and the reaction mixture becomes a homogeneous pale brown solution After stirring at room temperature for 3 hours the solvent benzene is stripped under reduced pressure (water pump) until the temperature of the product reaches 100 degrees C. The residual brown oil wh'ch solidifies to a tan wax like solid on cooling, may be conveniently divided into five approximately equal portions in tared 2,000 millilitre Erlenmeyer flasks. The crude product is then recrystallized with Nuchar C treatment using 455 millilitres of ethanol and 45 milli litres of acetone for every 85 grammes of crude material in order to separate the monocetyl phosphate from the dicetyl phosphate. The resulting off-white dicetyl phosphate may be further purified by two recrystallizations in the regular manner from ethanol to yield about 400 grammes of analytically pure dicetyl phosphate melting point 72 to 72 5 degrees C., as white pearly leaflets.

Sodium dicetyl phosphate is sparingly soluble in water more soluble in alcohol benzene toluene butyl ether and olive oil

Poppe (1954) gives the following methods of preparation of reactive polythene

(1) Sprinkle dicetyl phosphate powder on the surface of the film and draw over a hot plate regulated to approximately 90° C (the melting point of polythene is at 120° C.)

(2) The film may be dipped in molten dicetyl phosphate. Since dicetyl phosphate is water soluble, sterilization methods are limited A satisfactory method is to soak the film in 1 1 000 Zephiran (Benzalkonium chloride) for not more than 20 minutes. The reports of failures using the reactive polythene film do not give the method of preparation of the film and it may be that during sterilization the active agent was removed.

No plastic materials containing either simple plasticizers, such as dibutyl phthalate, or polymeric plasticizers for example polypropylene adipate should be used in the tissues, since in the course of time they leach out from the material with a resulting change in the physical properties of the implant The long term local and systemic effects on the tissues of such compounds liberated in low concentrations is not known

IMPLANT MANUFACTURE

Technique

One of the advantages of plastic materials is that they can be more readily worked than metals. Practical details of fabrication methods can be obtained from the manufacturers. Several points, however are worth emphasizing. Many of the techniques employed in metal working are applicable, but excessive heat production must be avoided. Cooling fluids should be used with care since they may be absorbed by some plastic materials. Great care should be taken that no undue stresses are set up in the implant at any stage in its manufacture all implants should be annealed. The use of solvents and adhesives should be avoided. Welding of plastic materials, while satisfactory for industrial purposes should not be employed as there is always the risk of a defect which may not be detected The chafing with a knife is liable to produce a crack which may " run " into the implant and at a later date cause failure It is advisable to fashion implants from a block of material. Any sudden changes in cross-section of the implant giving rise to

notch effects should be avoided in order to reduce stress concentration to a minimum. Data concerning a wide range of materials are available in an article published by Sargent (1947) and in the *Modern Plastics Encyclopedia and Engineers Handbook* published by Plastics Catalogue Corporation New York.

Acrylic resins can be polymerized into the form required, using plaster metal or wood patterns and simple plaster moulds, or if the shape is complex, in moulds made by the "lost wax" technique Techniques of polymerizing acrylic resins have been very widely developed by the dental profession by those who make cobalt-chrome castings for orthopaedic surgery and by the aircraft industry A wax which can be machined is available under the trade name of Okerin Wax No 1691 * Many waxes which are used in the "lost wax" technique have unsuitable mechanical properties to permit machining of thin cross-sections. Radiographs which are used for measurement in the design of an implant should be taken using the scanogram technique A diaphragm with a $\frac{1}{16}$ inch slit is placed over the aperture of the x ray tube. The tube is made to traverse the part with the slit at right angles to the line of traverse Since accurate measurement is possible only along this line separate radiographs have to be made of each dimension The tube to film distance should not be less than 42 inches.

Castings made from stainless steel alloys should not be used for implants The casting of cobalt-chrome alloys is a highly specialized technique and should only be undertaken by those who have long experience with the processes involved. All cobalt-chrome castings should be radiographed for casting defects and examined by a penetrant ink method for surface defects

Specifications and tolerances

Once the implant has passed the experimental stage, specifications governing the composition, the details of design the manufacturing processes, and the mechanical properties of the implant should be drawn up In the absence of a standard some inferior products will be produced as has happened in the past. A specification safeguards the manufacturer the surgeon and the patient Its preparation often stimulates further investigation which may result in an improvement in the performance of an implant. Failures will always occur with implants since their use is part of the surgical experiment However these failures can be reduced to a minimum by systematic investigations carried out both *in vitro* and *in vivo* before the implant is used in man. The whole question of standardization of materials and design of devices has been admirably dealt with by Barr (1954) in his presidential address to the Nineteenth Annual Meeting of the American Academy of Orthopaedic Surgeons, and his suggestions demand the most careful consideration In Great Britain the British Standards Institution has a committee which is preparing specifications for bone plates and screws.

SELECTION OF PATIENTS

The careful selection of patients for implant surgery is important. This subject is dealt with in detail in the chapters relating to specific branches of surgery It is

* Manufactured by Astor Boisselier and Lawrence Ltd., West Drayton Middx.

usually unwise to use an implant in children or adolescents particularly in orthopaedics They should be used only when there is a reasonable prospect that the use of heterogeneous materials will give a better result than reconstructive surgery employing autogenous or homogeneous tissues Implants should never be inserted until all infection in the area has been eradicated for at least 3 to 6 months Pre operative radiotherapy may result in the formation of a considerable amount of scar tissue and damage to the skin which may make the operative procedure difficult, and predispose towards infection and post-operative wound disruption Implants are often used after other surgical interventions have failed but their use should be considered at an early stage in the treatment and not as a last resort when the condition of the patient has deteriorated and the disease has advanced Excision of tumours, particularly of the skeleton with repair of the defect by an implant, even when metastases are present is justified providing there is a chance that the terminal stages of the patient s life will be made more tolerable

SURGICAL TECHNIQUE

The various subheadings in this section are fully dealt with in other chapters The success of implant surgery is dependent to a large extent on the surgical technique Often in order to insert an implant extensive dissections have to be carried out Minimal damage to the tissue planes is essential if differential movement between muscles is to be retained. The extensive use of diathermy for dissection and cutting can only result in considerable fibrous tissue formation While diathermy is useful for haemostasis there is always the risk that its indiscriminate use will result in haematoma formation in the post-operative period The use of high-speed tools, for example, in the cutting and drilling of bone, without adequate cooling with saline may cause death of the bone at the areas of contact with the implant. One wonders whether the advantages of speed are not offset in many cases by the lack of control of heat production and by the loss of "feel and precision attainable with hand-operated instruments Further with the use of high-speed tools on bone there is an increased risk of transferring metals to the tissues (Shaw and Scales, 1954) Bowden Williamson and Laing (1954) have shown that transfer of metal even with hand-operated tools can occur and that corrosion of stainless steel can be initiated in this way resulting in an inflammatory reaction of the surrounding tissues.

We have the prospect of great and new opportunities for conservative surgery but only a just appraisal of the hazards and a judicious selection of both patients and materials coupled with an appreciation of the biological and mechanical problems involved can prevent many disasters

ACKNOWLEDGEMENTS

I would like to thank Mr G J Ames of the Mechanical Engineering Department General Electric Company Ltd., Stanmore for much helpful advice Dr H Nothdurft of the Institute of Physiology University of Heidelberg, and Mrs E. T Oppenheimer of the Institute of Cancer Research, Columbia University New

York, for photographs and information concerning their work Dr H A. Sissons of the Department of Morbid Anatomy Institute of Orthopaedics, University of London for histological preparations, and Mr G D Winter Department of Biomechanics and Surgical Materials, for help in various ways in the preparation of this chapter I would also like to acknowledge the Medical Research Council and the Nuffield Foundation who have given grants to aid the work on which this chapter is based

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CHAPTER 6

BIOMECHANICS—ITS APPLICATION TO SURGERY

J M Zarek

INTRODUCTION

To be able to repair a machine the mechanical principles on which it works and the behaviour of the material of which the components of the machine are made must be well understood. This also applies to the human body in the surgical process of repairing what accident or disease have destroyed in man or what Nature simply did not provide. It is only recently that extensive surgical treatments have been embarked on and, although with a varying degree of success, the experience gained allows us to formulate more definite opinions in the systematic approach to these procedures. It is now recognized that, in the process of amputation or internal replacement of a faulty part of the skeleton, besides the surgical part the knowledge of mechanics stress analysis, mechanical and metallurgical properties of materials used, and the mechanical functioning, when performing normal physical activities, of the part of the skeleton to be repaired or replaced must be considered. This, however is part of engineering science and outside the ordinary knowledge of the surgeon. As some of the surgical procedures are becoming increasingly more complex, team work of representatives from several branches of science appears to become essential. The object of this chapter is therefore not to teach the surgeon engineering but merely to indicate the possible fields of work common to the surgeon and the engineer.

What is biomechanics?

Biomechanics (*see* Fig 50) in its general sense may be defined as the branch of science which applies the methods and techniques of mechanics to the investigations and analyses of the effects of the external and internal forces on the human body at rest and during movement under normal and pathological conditions. It comprises three main groups of activities (1) theoretical biomechanics (2) applied biomechanics (3) human engineering.

Theoretical biomechanics is concerned with the study of movement of the human body under normal healthy conditions. Its findings arranged systematically have many direct applications in various sports activities and military and industrial fields, although its greatest importance is in application to medicine. Here we have problems associated with the propagation of pressure waves, produced by the pumping action of the heart, in blood vessels or the flow of air in the respiratory passages and analysis of forces during breathing—the knowledge of which is very vital for the design of respirators for poliomyelitis cases.

In the field of aviation, to provide for the safety of the flying personnel, besides the design and working of safety equipment its effect on the human body when in operation must be considered. As an example the pilot ejection seat may be

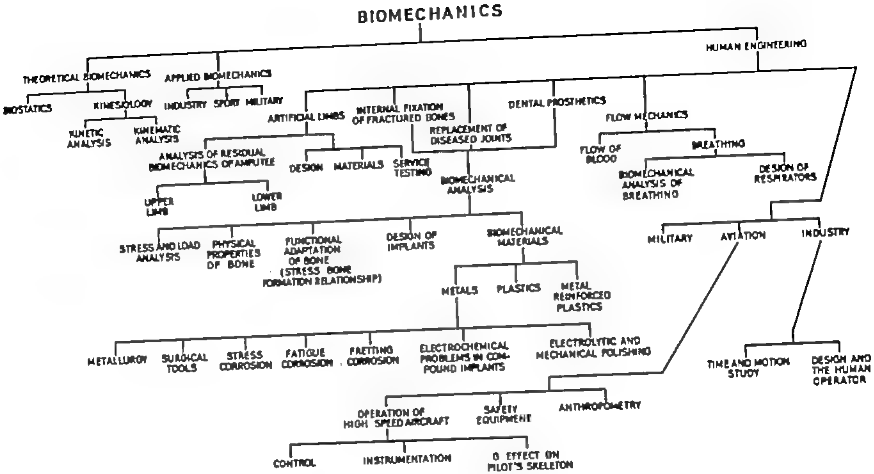


FIG 50.—Table of biomechanics.

mentioned and with it such problems as the acceleration effects on the skeleton of the pilot.

However its greatest importance lies in application to orthopaedic surgery in the process of various reconstructive procedures of the skeleton Here the operation may be an amputation or an internal replacement of part of a bone or a repair of a fractured bone It is now being recognized that these procedures require a great deal of biomechanical knowledge which makes full use of conventional engineering materials and techniques in a specific manner which can be defined as human engineering. Here the problem of the magnitude of forces carried by a bone or transmitted through a joint, the behaviour of bone itself under stress, the mechanical behaviour of materials used for implants, the design of the implant and its mechanical effect on the bone, and finally compatibility of the material must be considered as in ordinary engineering practice When the case is to be an amputation in addition to the above the degree of amputation must be analysed in terms of what we shall call the " remaining or residual biomechanics " of the limb concerned It is of no great assistance to the amputee to be equipped with the most up-to-date artificial limb if the residual biomechanical power is not capable of operating it efficiently It is therefore essential to consider amputation and fitting of the limb as a one-stage problem and to provide a replacement which will simulate the potentialities of the natural limb in a most exact manner

In this chapter however we shall limit ourselves to (*a*) the analysis of bone as an engineering material and its structure when subjected to the action of forces in the process of repair or reconstruction and (*b*) the analysis of problems associated with the behaviour of materials used in these processes with special reference to design of implants.

FUNCTIONAL SIGNIFICANCE OF FORMATION OF BONE

Every bone in the skeleton is at one time or another a load-carrying member although it is the bones of the lower limb which are the greatest load bearers as they are used in transporting the whole body from one position to another It must be noted here that the movement of the human skeleton, although its final result may be translational consists of a chain of rotary movements of the various parts of the body The forces responsible for this movement usually produce in the bone stresses which are tensile, compressive and shearing. They may be the result of a bending movement, direct force or a torque.

The formation of bone under normal conditions has been the subject of past investigations, in terms of the function it performs, with the purpose of determining whether stress has any effect on the natural growth of bone or not. In recent years, because of the tendency in orthopaedic surgery to replace bone by artificial materials like plastics or metals, the problem of the behaviour of bone under various conditions of stress received a certain amount of attention. However under traumatic conditions, in the process of repair of a fractured bone or in the case of a metallic replacement for a part of a bone the investigation into the law of growth of new bone at the bone implant junction is more complex.

Bone as an engineering material is not homogeneous and shows a marked degree of anisotropy A material is called anisotropic if its elastic properties are

not the same in all directions It is the anisotropy of bone that gave rise to the study of the functional significance of bone form in relation to stress

In 1867 von Meyer demonstrated sections of the upper part of the femur and discussed the significance of the trabecular orientation in it Culman an engineer who was present at that meeting, became interested in the analysis of this inner structure and concluded that the trabeculae of this bone as seen in the frontal plane were arranged along the lines of principal stresses produced by a force acting on the head of the femur He produced his famous diagram of a Fairbairn crane in which he computed the lines of principal stresses or the so-called stress trajectories.* He based his calculations upon his crane being made of a homogeneous solid material resembling the femur in shape and loading. He concluded that the femur was designed so that it could transmit a maximum load with a minimum of material This analysis has become the basis for the "Trajectorial Theory" of bone form and gave rise to the investigation of the functional significance of the orientation of the trabeculae. However as the trajectories apply to both compressive and tensile stresses, some investigators like von Meyer Roux and Wolf held the view that tensile stresses are responsible for the growth of bone while Jansen and Carey believed that the presence of compressive stresses stimulates the formation of bone. Triepel completely rejected the validity of the trajectorial orthogonality of the trabeculae in the bones Koch's analysis of the functional significance of bone form supports the view that the trabeculae arrange themselves along the lines of principal stresses He produced calculated results of principal stresses for the neck and the head of the femur when the head carries a concentrated load of 100 pounds

However an examination of his results suggests that they are not in agreement with either the theory of stress analysis or the assumptions he made for his analysis. He rightly assumes an oblique load which in the neck of the femur gives rise to bending, shear and direct compressive stresses (Fig. 51) The assumed concentrated load P (Fig. 51) may be resolved into two components—the direct compressive force R and the transverse force S In any cross-section on the length 0–0_1 of the neck force R produces a uniformly distributed direct compressive stress; while the transverse force S is responsible for shear and bending. The shearing stress distribution is parabolic—having a zero value of shear at the outer fibres in the frontal plane and reaching a maximum value at the centroid of the cross-section of the neck. The bending stress has a linear distribution and is of zero value at the centroid of the neck, reaching a maximum compressive and tensile stress at the outer fibres of the cross-section. Fig. 51 gives a graphical representation of stress distribution in section A–A, where the bending moment is zero and section B–B In section B–B the combined direct compressive stress due to the axial force R and the direct tensile and compressive stresses due to bending displace the neutral

* It can be shown that in a most general state of stress at a point in an elastic material there will always be three mutually perpendicular planes on which the shearing stresses vanish and the direct stresses have stationary (maximum or minimum) values. These direct stresses are called the principal stresses and their action may be tensile or compressive. In a two-dimensional or a plane system of stress there will be two mutually perpendicular planes on which the shearing stresses will vanish and the direct stresses will have maximum and minimum values. The directions of these direct or principal stresses which are at a point at right angles to each other are called the principal directions. It is possible to construct two systems of orthogonal curves whose tangents coincide with the directions of the principal stresses at each point. These curves are called "stress trajectories"

axis * or the line of zero direct stress from the centroid of the cross-section to a new position as shown by C. The magnitude of this displacement obviously changes from one cross-section to another as it depends upon the values of the bending stress and the direct compressive or tensile stress acting in a cross-section It appears that Koch in his analysis assumed the centroid of the cross-section as the neutral axis, disregarding the displacement due to the direct compressive stress Also in his diagram (*The American Journal of Anatomy* Vol. 21 p 249) for a point lying on the neutral axis Koch gives two different values for the principal

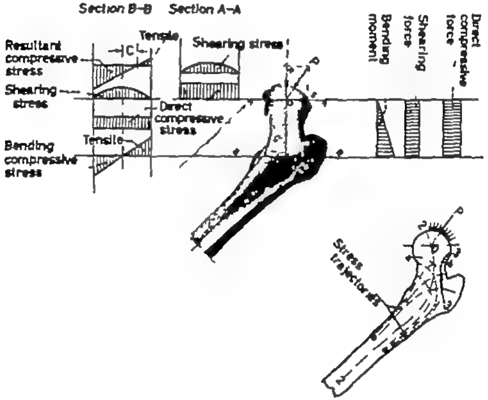


Fig. 51 —Diagramatic representation of forces and stresses in the neck of the femur

stresses. One according to his calculations, is 145 pounds per square inch and is compressive while the other he gives as 13 pounds per square inch and tensile. This of course is not correct as in bending due to transverse *loading at the neutral* axis in a cross-section the direct stresses are zero and only a shearing stress with a complementary shearing stress at right angle is present. This system of stress is equivalent to one consisting of two direct stresses, one compressive and one tensile, both equal in magnitude *to the shearing stresses but acting at 45 degrees* to the directions of the shearing stresses (Fig. 52).

Also on a certain length along the neck of the femur going from point 0 to 0_1 (Fig. 51) the direct compressive stress will exceed the value of the maximum tensile

* Neutral axis or plane defines the line or plane of zero direct stress. Only in bending of a straight beam or cantilever when the longitudinal forces are absent, the neutral axis coincides with the centroid of the cross-section.

stress due to bending, and therefore on that length of the neck there will be no neutral axis. With Koch's assumed loading the approximate outlines of the neutral axis should follow the line 3–3 in the right hand diagram of Fig. 51

It is unfortunate that Culman's idea of the Trajectorial Theory has received so much attention as it can be criticized on the following points In the analysis of stress it is always assumed that the material is homogeneous, which is not true about bone The analysis as put forward by Culman is that of plane stress or two-dimensional although in fact it is a case for a three-dimensional analysis The assumptions in Culman's analysis refer to static conditions of loading in the frontal plane while the load on the head of the femur is mostly of a dynamic nature with its direction of action oscillating appreciably This suggests that the frontal cross sectional plane which Culman used for his analysis, need not

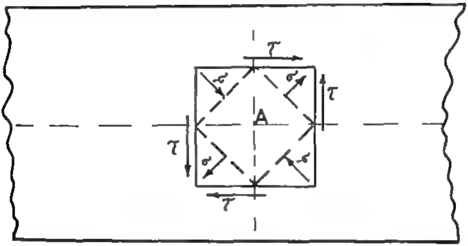


FIG 52.—Diagram showing that a system of pure shear ( ) at point A is equivalent to a system of direct stresses, one tensile and one compressive (σ), acting on planes at 45 degrees to the planes of pure shear

necessarily be one of the principal planes and the directions of the principal stresses need not be parallel to the frontal plane Further the intensity of stress along each trajectory is greatest when it is parallel to the longitudinal axis of the neck of the femur and diminishes to zero at the point where the trajectory cuts the outer fibre of the bone at right angle (Fig. 51) In view of this it is also difficult to accept the idea of those who believe in the mechanical adaptation of bone, that is, that the trabeculae lie along the paths of maximum stress within the bone and thus transmit a maximum load with a minimum of material

MECHANICAL ANALYSIS OF THE FEMUR

As a load bearing bone the femur is one of the most important bones of the human skeleton and it is subjected continously to the action of mechanical forces which are usually of a dynamic nature causing frequent fractures. It is therefore not surprising that the femur has been investigated more extensively than any other bone and in recent years the surgical procedure of the Judet brothers with regard to the reconstruction of the upper part of this bone has stimulated further investigations.

distributed so as not to give rise to points of high stress concentration on the bone, as they act in directions which are not in line with the anatomical line of action of forces in that bone. It may be noted here that the longer the intramedullary nail the smaller will be the reactive forces of the couples. To avoid any stress concentration effects the changes in the cross-section of the prosthesis were made

FIG. 54.—Judet type of prosthesis *in situ* showing the reactive forces acting on the bone.

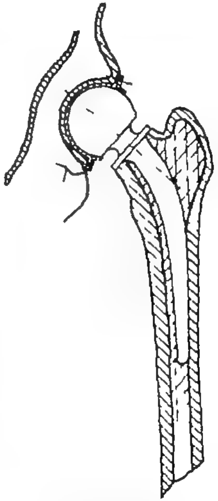


FIG. 55.—A ball and socket replacement of the head of the femur.

gradual. *The described prosthesis was used in a patient in 1954 and is giving a* very satisfactory service showing a rapid formation of new bone along the medial and posterior part of the prosthesis which coincides with the region in which a compressive force acts on the bone (Fig. 56*a* and *b*).

Many clinical cases did not fail mechanically where the head of the femur only was replaced by a Judet type prosthesis; however, pain in the joint and loss of movement were recorded. In cases where the whole neck of the femur is replaced by an implant this complication appears not to be present. Fig. 55 shows a simple

design of a "ball and socket" joint The socket is fixed into the acetabulum by means of screws and so provides free movement of the head of the hip-joint in a metal to metal combination Although the diagram shows a design where the bone implant junction takes place along the neck of the femur it appears that a better solution would be to use an implant which combines the "ball and socket" arrangement with a method of fixation to the shaft shown in Fig 53*b* and thus secure a more favourable distribution of forces Fig. 55 was drawn for the con-

(*a*) (*b*)

FIG. 56.—Formation of bone can be seen in (*a*) the posterior part and (*b*) medial part of the shaft, that is in the parts where compression is present. (*By courtesy of A C Bingold, F.R.C.S.*)

sideration of those surgeons who feel that if a large part of the neck of the femur is left, and should a complication occur an arthrodesis is still possible

My experience extends only to cases where either the upper part of the femur was replaced by a large metallic implant or the lower one in a form of a metallic knee joint. It should, however be possible to replace a certain length of the shaft of the femur by a metallic implant quite successfully leaving the two joints undisturbed In such a case the length of the shaft to be removed could be made of a porous metallic structure resembling in shape the removed bone Fixation of both ends could be secured either by a collar and an intramedullary nail at each

end or by means of three short side plates at each end, made as a part of the metallic insert, and screws The design of the porous part of the implant should be so arranged as to stimulate growth of bone into the implant and so form a united structure

SUMMARY

The brief analysis of the up-to-date trends in the surgical replacement of bone by implants shows that although a lot has been achieved, there still remains a multitude of problems to be solved. However we are now at least in a position to classify them in a more organized manner On the anatomical side we have the problems of (1) analysis of forces in load-carrying bones (2) bone formation-stress relationship (3) analysis of conditions at the injury and, for instance, the importance of the *p*H value of the body fluids in trauma (4) tissue reaction to the material of the implant. The implant itself however carries the greatest number of problems. Here we have the problem of (1) the design of the implant (2) the material to be used (3) the method of manufacture of the implant (4) the final treatment of the prosthesis.

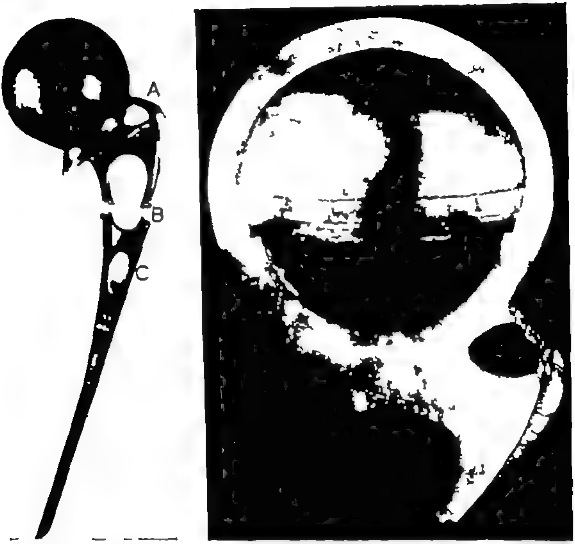
The choice of the material used is more critical in compound implants, that is in cases where more than one part is required. Stainless steel when used for a single implant may prove to be satisfactory although the manufacturing process here may be of great importance For compound implants this material is considered unreliable If stainless steel is used as a reinforcing material for a plastic material the design must be so arranged that the steel part will not, for instance, be partially in the bone and partially in the plastic. Such a situation would cause a rapid corrosion of the steel part due to conditions of differential oxygenation Normally in such cases the part covered by plastic will lack oxygen when compared with that part which will be say in the bone and will become anodic with regard to the remaining part.

Faults caused by manufacture

Further it is not always appreciated that the processes of casting of steel and welding carry a great number of precautionary steps which must be considered if the material of the implant has to preserve its original mechanical properties. Fig. 57*a* and *b* may serve here as an illustration. It represents a micrograph of a cross-section of a part of a Moore's prosthesis which was made of stainless steel of the 18/8 FMB variety. Because of the complexity of the shape the lower part was cast while the upper portion was machined Because of faulty casting and lack of heat treatment the lower part no longer showed the same mechanical properties as the original FMB material and the prosthesis failed in the course of a few weeks after insertion The sudden changes in the cross-sections of the prosthesis at such points as A–B–C during casting cause internal stresses due to a non uniform contraction during solidification and cooling. These stresses in castings should be removed by annealing at temperatures high enough to permit plastic readjustment of the metal It must also be noted that the grain size of the cast part is much greater than that of the upper part of the head of the prosthesis which was machined

The micrograph shows that the upper machined part and the cast part of the

prosthesis were welded. Stainless steels, when heated to a temperature in the range 500°–800° C, are subjected to structural changes which have effect on their resistance to corrosion although their mechanical properties may not be affected appreciably. This condition when a portion of the metal is heated in the zone of 500°–800° C usually occurs during welding and the effect is referred to as "weld decay".



(a) (b)

FIG. 57.—(a) A broken Moore's prosthesis. (b) a micrograph of the head of this prosthesis. (*By courtesy of the Editor, Proceedings of the Royal Society of Medicine.*)

The effect of weld decay in stainless steel may be prevented by: (1) heating the whole prosthesis to a temperature of 1 000–1 150° C and quenching; (2) the addition of silicon, molybdenum and tungsten as ferrite forming elements; (3) reducing carbon content to 0·05 per cent; (4) producing other carbides—that is adding such elements as titanium, columbium, molybdenum or tungsten which have a greater affinity for carbon than chromium.

In general stainless steel owes its resistance to corrosion to chromium. However it must be remembered it is not due to the inertness of chromium as it combines very readily with oxygen but is due to the oxide layer which forms a protective film for the metal. This oxide film is subject to mechanical destruction and if the prosthesis under "service" conditions has its oxide layer continuously disturbed, corrosion will proceed.

The example in Fig. 57*a* and *b* is used to illustrate some of the problems which must be considered in the replacement of bone by a prosthesis. It shows clearly that the problem of design, material and method of manufacture of the prosthesis are inter-related and must be considered jointly

Apart from stainless steel, cobalt-chrome-molybdenum alloys are being used with good clinical results and it is felt that they will replace stainless steel in the future. However these alloys are not trouble free and an ideal material has not as yet been found. Materials like titanium, tantalum and zirconium offer great possibilities especially titanium, which is becoming more plentiful at a reasonable price

Use of metals

As this book is concerned with modern trends in surgical materials, outlines of up-to-date thoughts on the use of metals in the human body conclude this chapter

Some people have come to condemn the large operative orthopaedic procedures of metallic replacement of bone without being analytical about them but just because their results were not encouraging. Others felt that the problem in such procedures is connected with that of toxicity or is of electrochemical nature. The effect of the mechanical state of these materials on their behaviour in the human body has not received any attention as all the investigators were either physiologists, chemists or anatomists. It is, therefore, not surprising that the problem of suitable design of implants has been overlooked, although to a great extent it determines the method of their manufacture where the problem of metallurgy and heat treatment of the material used must be carefully considered.

It is true to say that experimental work on the behaviour of metals in body fluids carried out in the past in every instance refers to materials in unstressed condition and the effect of stress on corrosion has been overlooked. However it is recognized that very often materials although resisting corrosion quite well when in unstressed conditions may behave differently when subjected to the action of a corrosive medium while being stressed. The term "stress corrosion" implies simultaneous action of static stress and corrosive medium. Under such conditions it is generally accepted that the mechanical properties show a greater degree of deterioration than if the actions take place separately and then their effects are added.

Further in the majority of cases the implants are subjected to fluctuating stresses, and the fatigue limit of the material defined as the maximum value of the amplitude of the stress cycle which may be applied indefinitely without causing failure, must be considered Here again corrosion fatigue describing the simultaneous action of corrosion and fatigue must be accounted for as it has been found that corrosion of a material without the presence of cyclic stressing is not so rapid as when corrosion and stress act together Cyclic stresses cause break up of the protective oxide film and thus permit the corrosive fluid to produce pits in

the metal These pits may take the form of small intercrystalline cracks causing a considerable stress concentration at their roots and often are referred to as "stress raisers" These stress raisers cause a more efficient destruction of the oxide film and so the cyclic stresses and corrosion pits reinforce continuously their effect till the fatigue limit of the metal is exceeded and failure takes place

The above considerations are quite satisfactory in ordinary engineering practice where strength is normally accepted as a measure of success. In the application to the human body we must go further We must arrive at a criterion of compatibility of the metal to the living cell or in other words have an answer to the question why in some cases the living cells will not only tolerate the implant but will attach themselves to it The view is expressed here that it is reasonable to assume that the answer lies within the field of the theory of surface potentials of metals and the electrical properties of living cells

Although being concerned with the metal only it may be of interest to note here that many problems in this field still await solution We have found that the problem of final surface treatment of implants is very critical Examination of stainless steel, titanium, zirconium tantalum and cobalt-chrome molybdenum alloys subjected to various types of mechanical polishing or electrolytic polishing show very marked differences in the measured surface potentials when immersed in physiological fluids. In electrolytic polishing various polishing solutions and different current densities used in this process can result in a difference of a surface potential for one metal in a range of several hundred millivolts. Also local cold working of one piece of metal may result in a local difference of potential. Bending, say a plate, it was found that a marked difference of surface potential will be measured between the tensile and the compressive side of that plate.

Concluding this short review we see that biomechanics does not limit itself to the application of mechanics to the human body but for the complex surgical procedures of today it provides well-established engineering techniques for reproducing actual "service conditions of the implants Actual service conditions" implies a situation where a number of chemical and electrochemical reactions and reaction products are involved at a point following trauma and during the healing process The pH value during this process may undergo changes ranging from 7·4 to about 5·4 However here biomechanics leave and the surgeons come in.

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CHAPTER 7

ABDOMINAL SURGERY

A LEE McGREGOR

SURGICAL MATERIALS are of concern to the abdominal surgeon in the following circumstances for application to the surface of the abdomen, for example, colostomy and enterostomy appliances for use in the abdominal wall in the form of suture materials and mesh and for use in the abdominal cavity for example, sutures drainage tubes and bile duct tubes.

EXTERNAL APPLIANCES

Apparatus of some kind is needed in the management of fistulas which open on the surface of the abdomen and which may occur as a complication of disease or operation or may be made by design to serve a temporary purpose or as a permanent measure. Fistulas or sinuses opening to the exterior from the upper small intestine or from the pancreas contain powerful digestive juices which irritate the skin and lead to ulceration. The aim in these cases is to endeavour to neutralize the irritant effluent and to protect the skin. The latter object is obtained by protecting the skin with a mineral non-digestible substance such as Vaseline which is applied thickly over the area reached by the discharge. Furthermore this discharge is removed before it impinges on the skin by inserting an appropriate tube or catheter into the opening and applying continuous suction.

Ileostomy openings

Ileostomy openings are often required to be permanent and this necessitates the application of a well-fitting bag over the protruding end of bowel. The bag is usually made of rubber and fixed to the skin by a cement substance. An example is that of the Torbot ileostomy outfit which consists of a rubber bag and a plastic ring. The bag has two openings. The one below is for emptying and the upper one is maintained in place over the stoma and held open by a flange that encircles the central opening of the plastic ring. Metal fastenings on the ring connect it with an elastic belt. The apparatus is provided with an adhesive compound to maintain the position of the ring and to make the connexion of the ring and skin both water and air tight. The adhesive is harmless if time is allowed after each application for the solvent to evaporate.

Fox and Brush (1954) pointed out the desirable features in any device for use with an ileostomy or a colostomy. The apparatus should be easily applied, light and odourless, it should not distort body contour or bulge clothing, it should possess no irritating properties to macerate or irritate the skin around the stoma, and it should be easy to empty or dispose of.

Rubber *does not have all these* desiderata and sometimes extreme irritation can affect the skin when it is used. In order to avoid the allergic reaction of the skin

to rubber plastic material was tried To seal the bag to the skin a foam rubber pad was used and this was found to be non irritating, clean, easily washable and provided a satisfactory seal against leakage A Plexiglass cone with an incomplete rim was developed to direct the drainage downward into a bag which is made of odourless, disposable plastic material held in place simply by a rubber compression ring The apparatus comprises (1) A foam rubber pad (2) Plexiglass cone (3) Plexiglass belt frame (4) plastic collecting bag and rubber ring which is held in place by a waist belt that keeps the device snug and airtight. It requires no cement and is easily put on or taken off The following technique is advised

> The skin is washed and dried and a little talcum powder dusted on. The foam rubber pad with the Plexiglass cone and frame, is then applied. The belt is snapped on to the frame and a plastic bag placed over the cone and a rubber compression ring applied over the rim to hold the bag in place.

All this is done in a minute or less—much less time than the messy prolonged procedure required with rubber adhesives No odour escapes The bag is readily removed by stretching the rubber ring to allow the bag to escape from the cone the bag is then discarded. The character of the contents is visible through the plastic. The bag can be applied 4 days after operation and is equally useful for colostomy cases *

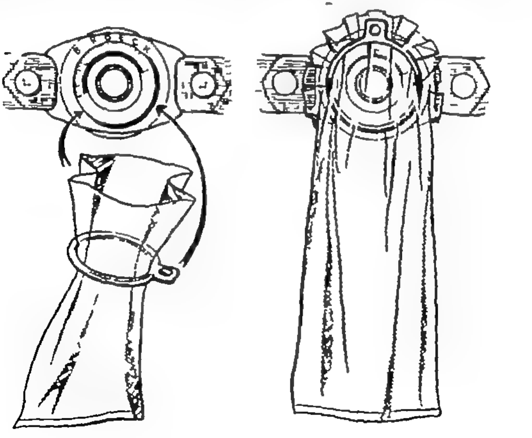

Fig. —58. A simple ileostomy appliance.

* The apparatus is called the Royal Ileostomy Appliance and is made by the Royal Surgical Appliance Co., 230 Washington Square Building, Royal Oak, Michigan, U.S.A.

Colostomy openings

There are different types of apparatus used to dress colostomy stomas and to act as reservoirs. They are well known and require no description. The author has found the most satisfactory and unobtrusive dressing to be a square of Vaselined surgeon's lint laid over the stoma and covered by a small square of waterproof material such as batiste. This is held in place by a narrow "two-way stretch" which has been cut up one side. The opening is made to close with push buttons. A light perineal band prevents the dressing from moving upwards. This apparatus was devised by a young doctor with a colostomy. He carries on a busy country practice and finds his plan works admirably. Many surgeons advise a routine daily colonic irrigation to clear the bowel and encourage evacuation at a convenient time. A douche can with a rubber tube and catheter attached is all that is necessary. The patient stands over the toilet wearing a rubber apron which directs the effluent into the pan.

The Xaid Colostomy Set * facilitates periodic colonic irrigations through an artificial anus and so achieves a certain amount of continence. It consists of (1) A circular shield made of a transparent plastic which is firmly held to the abdomen by an elastic belt. It has two projecting tubular parts—through the smaller a rubber catheter is passed into the stoma. The larger tube has an internal diameter of 45 millimetres and is connected by a thin-walled rubber tube of any desired length to carry the effluent to a receptacle such as a water closet. (2) An unperforated plastic disc which is worn over the stoma when this is suitably covered with disposable absorbents. It is worn in the intervals between irrigations.

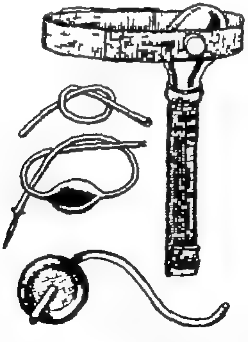

FIG. 59.—A colostomy belt showing tubes for douching and irrigation.

* Xaid Colostomy Set, Professional Products Co. 4103 Commonwealth Avenue, Toledo 12, Ohio, U.S.A. Conforming to the rules of the Council on Physical Medicine and Rehabilitation of the American Medical Association for inclusion in apparatus accepted.

Biliary fistula

Bile drainage for shorter or longer periods is a common surgical procedure and with early ambulation there is the problem of the collection of bile Browne and Locke (1953) stated that a bile-collecting receptacle should be light and sturdy non-compressible, non-spillable comfortable to wear and admitting of drainage without being removed and without disturbing the patient They conceived the idea from the hip pocket flask of prohibition days which conformed to the body shape. The container is made of transparent rigid plastic and holds eight ounces of fluid. It is attached to the patient by adhesive strips which fasten into slots built into the edges of the container Three tubes are incorporated in the latter The bottom one is for drainage. A short rubber tube attached to it is clamped or opened as required. Of the two tubes at the top one connects with the tube coming from the patient To the other a finger stall is fixed with a rubber band The finger stall is pricked with a good sized needle to prevent air lock.

DRAINAGE THROUGH THE ABDOMINAL WALL

Tubes passing through the abdominal wall may drain a part of the abdominal cavity or drain a viscus or a duct

Drainage of the abdominal cavity

Drainage of the abdominal cavity is practised much less frequently than heretofore because of the part played by antibiotics in overcoming infection. However this form of drainage is still necessary when a collection of fluid or pus exists or when a leak is expected, for example, after operations on or in the vicinity of the pancreas For these purposes some form of rubber is in general use This may be a tube or catheter corrugated rubber or glove rubber The Penrose tubular thin rubber drain with a wick of gauze passing through it is valuable and non irritating. A sump drain is used especially after operations where leakage of digestive fluids may occur This may be a rubber tube with a catheter (with a number of holes in the distal end) extending throughout its length Suction is applied to the catheter Cleland (1954) has devised a plastic sump drain. It is made of a flexible plastic material (Portex vinyl ether) which allows the tube to move comfortably with movement of the patient and it can lie in a devious track. The outer sump portion has a diameter of not more than 1 centimetre It has the shape of a test tube with multiple holes in the distal blind end. An inner or suction tube passes nearly to the end of the sump and is held in place by a collar the fit being tight enough to prevent the inner tube from falling out and yet be removable for cleaning. There is a small hole in the collar to prevent the formation of a vacuum. The length and diameter can be arranged at will The apparatus is useful for draining large dead spaces abscess cavities, oozing areas, or pancreatic or intestinal leaks

TUBES PASSING FROM A HOLLOW VISCUS TO THE EXTERIOR

These tubes serve a variety of purposes such as the control of haemorrhage, feeding, and drainage or decompression

The control of haemorrhage

In portal hypertension bleeding from oesophageal varices frequently constitutes a surgical emergency. Whereas the definitive treatment of the condition is some form of decompression (porto-caval or spleno-renal shunt) or a direct attack on the bleeding area, the patient's condition often does not allow such severe measures. It is here that the Blakemore Sengstaken tube is of value.

Sengstaken and Blakemore (1950) produced an apparatus for the control of bleeding from oesophageal varices. It has long been known that the pressure necessary to collapse oesophageal varices is very low and that if enough traction is made on a naso-gastric tube bearing an inflated balloon which lies in the stomach haemorrhage will cease because the balloon compresses the junction of the coronary veins of the stomach with the oesophageal veins and shuts off the ascent of portal blood. *The pull on stomach and oesophagus caused by the traction on the tube* sets up reflexes which ultimately lead to regurgitation of the tube. It is also known that a balloon pulled up against the cardio-oesophageal junction tends to bulge into the oesophagus. Likewise an oesophageal balloon will prolapse partly into the stomach. To prevent over expansion of the lower part of the oesophageal balloon which projects into the stomach Sengstaken designed a balloon in which the lower third was reinforced with a double thickness of rubber. The apparatus consists of a tube with a generous lumen for gastric suction or feeding. It has attached an oesophageal and a gastric balloon each connecting with a fine tube let into the wall of the gastric tube to allow inflation or deflation of the balloons. The tube is passed to the 50 centimetre mark and the gastric balloon inflated. Gentle traction on the tube meets with resistance, showing that the tube is in the cardia. The oesophageal tube is then inflated to 20–25 millimetres of mercury and this pressure is maintained by clamping the related tube. The apparatus is a valuable adjunct to surgery and is life saving but it requires meticulous observation of several points to be successful. Sedation is necessary, the head of the bed must be elevated, and to prevent displacement of the tube the patient must not swallow even saliva. Full directions and a formula for gastric feeding are supplied with each tube.

Injury to the oesophagus can follow the use of almost any tube, but this does not lessen the immense value of the apparatus. In 1954 the author was shown by Blakemore a case of portal hypertension with oesophageal bleeding in which the tube with balloons had been in place for over 100 days. A good modification the writer then saw was the use of a disc of sponge rubber about an inch in diameter and half that thickness with a hole in the middle through which the tube passed. This held the apparatus in place against the nose and no strapping was necessary on the face.

Tubes for feeding or for draining the intestinal canal

The Levin tube size 14 and 16 Fr. gauge and 50 inches long is in general use for stomach drainage. Another tube is Einhorn's, bilumen, india rubber 16 Fr. gauge, 48 inches long, with a lead rubber end 2½ inches long which is used for jejunal feeding or drainage or for gastric drainage.

The well known Miller Abbott tube is a 10-foot tube with a balloon at the end which is inflated with air once it has passed the pylorus. It has been invaluable

in the treatment of intestinal obstruction It is important that it should not pass more than 4 feet beyond the pylorus as it may project from the anus. The gut concertinas itself on the tube and if too much tube is swallowed it may pass the entire length of the alimentary canal

The author s assistants have found a smaller percentage of failures when using Cantor s (M O) india-rubber 18 Fr gauge 10-foot-long tube with a mercury balloon at the end. There are four holes at the balloon end 1 inch apart and a further four holes 1 inch apart starting 8 inches from the balloon The tube is marked S (stomach) at 17 inches P (pylorus) 24 inches, D (duodenum) 30 inches from the balloon. It is also marked with rings at 4 5 6 7 8 and 9 feet Spillage of the mercury has not produced any trouble

Trimble and Nouri (1955) have introduced a new technique combining drainage and feeding in gastric surgery Any such apparatus should be comfortable and non-irritating to the patient, it should drain the stomach and the two jejunal limbs, obviating any strain on the suture lines, and it should permit all fluids and feedings to be given through the tube from the end of the operation The several types of double lumen tubes available do not fulfil all these requirements The tube they have devised does do so The apparatus consists of two polyvinyl tubes of small calibre (12 Fr) tied together and inserted before operation through one nostril When the jejunum is anastomosed end to-side to the stomach, tubes are drawn through the open gastric stump after the posterior suturing is complete. The three silk ties fixing the tubes together are cut freeing the catheter

The catheter dyed red at both ends and stamped Suction is let down 20–25 centimetres into the proximal limb to drain duodenal, pancreatic and biliary secretions. There are additional holes in the catheter to drain the gastric stump The catheter dyed blue at both ends and stamped " Feeding " is let into the distal limb for 20–25 centimetres it can also be used for suction if needed Similar arrangements can be made for a Billroth 1 hook up the suction tube being in the stomach and the feeding tube in the duodenum. The method avoids the disadvantages and dangers of intravenous feeding. All dietary requirements can be given through the feeding tube immediately after operation. Thirty four drops a minute (2 millilitres) gives 2,880 millilitres in 24 hours. Forty-eight hours after operation a high protein and high carbohydrate diet is given through the tube and is usually continued for 4–6 days. " Suction is connected to gentle bedside suction and can be clamped as necessary leaving Feeding " undisturbed. The body electrolytes return rapidly to normal and the tube has given complete satisfaction

SUTURE MATERIALS

The general facts relating to suture materials are dealt with in Chapter 16 Here they are discussed in their application to the abdomen.

Catgut, silk, linen, and nylon have all been used and continue to be popular Catgut is an absorbable material which was its great asset in times when sepsis was common in surgery This makes it valuable today when there is fear of sepsis such as that which occurs in contaminated or infected wounds or when surgery is performed under conditions which are not ideal In general animal protein suture material such as catgut or silk is more irritating to tissues than is

vegetable fibre such as cotton. Thus in intestinal anastomoses fine catgut produces a mild local inflammatory reaction which makes it the material of choice for obtaining rapid leak proof peritoneal adhesion of opposing surfaces. Where, however there is fear of digestion of catgut by intestinal juices, a non absorbable layer of sutures is mandatory such as in closure of the duodenal stump In closure of the peritoneum catgut has value for the same reason It should be fine (0), mounted on atraumatic needles, and reinforced by an additional suture at distances 1 inch apart The filaments of non-absorbable sutures such as cotton or silk may be penetrated by bacteria which find harbourage between the fibres of the material (Mu and Pai 1942) Infection results and persistent sinuses are thus formed. These do not heal until the suture is extruded or removed Hoback (1952), discussing the closure of abdominal wounds, stated that the requirements of an ideal suture material are as follows (1) It should hold the wound edges together till the wound is healed (2) The suture should not be affected by or take part in any untoward reaction during healing. (3) The suture should be absorbed or become innocuous after healing.

Metal sutures

The cardinal factor in the choice of a suture material should be the response of the tissues to it. Ligatures of gold were used by the ancient Greeks and metal sutures have been used for centuries. Silver wire was used successfully in the presence of tension or friability of the tissues. It is brittle, tarnishes, and has poor tensile strength.

Steel wire

Steel wire was introduced into surgery by Babcock (1934) He stated that because of its resistance to chemical change, modern alloy steel has been called the noble metal. The wire has marked tensile strength and will stretch a third of its length without breaking. It can remain buried in the tissues for long periods without tarnishing. Wire of 36 or 35 B & S gauge (0·0007 inch) is like a fine hair and has a tensile strength of 2½ pounds It may be used for ligation purposes or delicate suturing. Gauge 30 B & S has a tensile strength of 15 pounds and may be used in the abdominal wall. Preston (1940) showed that wounds closed with steel wire produced less tissue reaction than any other suture material. The wire maintains a passive role even in infected wounds and interferes in no way with secondary wound healing even in the presence of complications. Large (1943) pointed out that the reaction of tissues to various sutures is influenced by the number and type of organisms present, the vascularity of the tissues, the general nutrition and the presence of foreign bodies other than sutures. One or other of these factors is often blamed for infection and disruption when the technique or the choice of the suture material is at fault. Metal, being a single filament, cannot harbour bacteria and healing occurs even in the presence of pus. Hoback (1952) does not advocate steel wire as a routine in abdominal wound closure He advised it (*a*) when actual or potential wound infection exists (*b*) when disruption is feared (*c*) in advanced age (*d*) in carcinomatosis or cachexia (*e*) in jaundice when there is drainage of bile, pancreatic or other digestive ferments.

Certain rules which must be observed in the use of steel wire sutures are as follows (1) The tension to use is that which approximates tissues and does not

constrict them (2) Kinks must be avoided as they diminish the tensile strength (3) Knots must be squared and the points turned down carefully

Kaufman, Johnson and Lesser showed as far back as 1939 that patients in whom wire has been used may be exposed to diathermy or x rays without untoward effects. Wire is valuable in perineorrhaphies and the repair of vesico-vaginal fistulas

In a series of hernial repairs infection occurred in 24 per cent of cases in which only catgut was used in 11 per cent of cases where catgut and wire were used but there was no infection where wire alone was used.

Madsen (1953) in experiments in animals and man found that silk cotton linen and stainless steel wire are the preferable materials for use in the closure of wounds in fascia.

Robinson (1952) showed that continuous wire suturing is preferable to interrupted and figure of eight sutures which produce pain tissue strangulation and shearing forces which will cause breaking of the wire Over 4 years, using wire in abdominal surgery their results were excellent in 505 patients There was wound sepsis in 3 patients but no case of wound disruption after 1 year Hoxworth Sullivan and Guiseffi (1954) set out to show that flexibility in suture material is in some respects undesirable. They propounded a new theory based on engineering principles, that the factor of shear' upon fascia by the flexibility of suture materials produces cutting and tearing through fascia and is a factor in wound disruption The experimental results showing the effects of flexibility and rigidity upon the holding power of suture material were in accordance with the theory showing the superiority of rigid wire in preventing wound dehiscence A rigid wire suture is therefore still better than one of flexible wire This is borne out by the usefulness, rapidity and ease of the method in the closure of abdominal wounds in 161 patients. The material is its own needle so that cutting into lengths threading needles, tying knots and waste are eliminated.

Toone (1955) reported the unusual case of a female patient who developed what appeared to be strangulation in a huge hernia resulting from a previous abdominal operation. The cause of the symptoms was found to be peritonitis in the sac due to perforation of a loop of small gut from the ends of a steel suture which had been used in closing the rectus sheath. Interrupted sutures had been used.

Summary

As suture material for the abdominal wall, catgut is being used less and less in favour of unabsorbable material such as cotton linen and monofilament steel wire The latter is gaining in popularity and is the best substance yet found in the prevention of post-operative wound disruption.

THE SURGERY OF HERNIA

Many different materials are now used in the repair of various types of hernia. Whatever the qualities of the substances may be none in any way alters the basic principles of repair The aim of the surgeon is to restore the *status quo ante* where this is possible not to use tension, and not to deviate muscles from their lines of action. The Bassini operation for inguinal hernia marked a great advance in the treatment of this condition in that it separated the internal from the external ring

as far as possible and reinforced the posterior wall of the inguinal canal. The deviation of the line of action of the conjoined tendon by approximation to the inguinal ligament is, however an abrogation of surgical and mechanical principle. The muscle straightens out to its pre-operative position when subject to any stress. It is now appreciated that it is sounder to strengthen the wall of the canal by inserting a lattice work to act as a scaffolding for the growth of fibrous tissue, or to insert a mesh of some foreign material to serve the same purpose The newer substances in use for this purpose are floss nylon, steel wire, nylon mesh, tantalum mesh, Fortisan, and polyvinyl

Floss nylon

Nylon thread has been used in surgery since 1946. Monofilament nylon has some rigidity and knots may slip Braided nylon is better as it is more pliable. Floss nylon is composed of fibrils similar in size and number to those in floss silk. It is soft inert smooth, pliable easy to work with and can be repeatedly boiled (Monro 1952) Monro has used it in closing abdominal incisions and repairing hernia and wound healing has occurred without extrusion.

Steel wire

Abel and Hunt (1948) advised the use of stainless steel alloy wire which was introduced by Babcock (1934) For closure of abdominal incisions and large scar hernias they use monofilament standard gauge 31 or 32. For inguinal or femoral hernias 33 or 34 are used. In over 2,500 abdominal incisions, in patients mostly debilitated, there has been no instance of wound disruption or post operative hernia. In 300 hernias done over a period of 4 years there has been no recurrence. The tissues react to its presence by the formation of fibrous tissue only over a narrow zone There is no inflammation or foreign body response. Stay sutures are never necessary The wire can be used in the presence of infection One of the most compelling factors in its use is the elimination of post-operative wound disruption. This occurs, when wire is not used, in about 1 per cent of laparotomies and the mortality is 40 per cent.

Abel and Hunt use the wire routinely in abdominal closure, for large incisional hernias, and for all hernias requiring reinforcement

The principles to be observed in the use of wire are the avoidance of distortion, which implies tension and therefore necrosis, the avoidance of kinking, and tying taut but not tight.

In hernial defects a steel darn is used It is not necessary to carry out an extensive dissection to define the layers forming the ring. If as rarely may happen, the point of a broken wire causes discomfort, it is removed under local analgesia.

Ryan (1953), reporting from Shouldice Surgery Toronto stated that steel wire was adopted as the routine for hernial repair In 369 patients with recurrent hernia there were no recurrences within 1 year

The writer can testify to the immense advantages of steel wire from his experience in large hospital and private practice, when used as defined above There have been no complications in a period of 5 years from the use of wire, no recurrence of hernia, and the only case of abdominal disruption occurred in an old man where wire had not been used.

Mesh

Several varieties of mesh have been and are being used as reinforcing material in the repair of incisional or other types of hernia The method is an old one for silver filigrees were used many years ago It is interesting that at reoperation many years after their insertion such filigrees were found to be loose and lifted easily from the tissues. Koontz and Kimberley (1950) showed in animal experiments that steel mesh was not very resistant to infection and that fibrous tissue does not infiltrate the mesh which becomes surrounded by dense scar tissue producing a tumour-like effect

Tantalum mesh

Tantalum was introduced into surgery by Burke (1940) Lam, Szilagyi and Pappendahl (1948) showed that fibrous tissue grows through the interstices of the mesh and surrounds it they advised its use in the repair of hernia It has been used for repair of defects of the diaphragm and for full thickness defects of the chest wall

Tantalum is a biologically inert, malleable, non-corrosive, and non absorbable pure metal of atomic weight 181·4 and atomic number 73 It stimulates a cellular response when implanted in the tissues of the body and becomes covered by adherent fibrous tissue. Its main uses in surgery are as plates, screws, or foil The first products were grease coated and required scrubbing before use The new type does not need degreasing. Flynn Brandt, and Nelson (1951) in a 55 months follow up after the use of tantalum mesh in 45 cases of ventral hernia reported but one recurrence and this was not in relation to the mesh. They advised the turning down of a ½ inch cuff at the edges of the mesh to anchor the sutures. The mesh is fixed with 000 tantalum braid at its edges and in the centre. Early ambulation is practised. Fragmentation may however occur due to body movement.

Koontz (1951) advised the use of tantalum mesh to close large defects when the edges cannot be approximated or to reinforce weak areas He pointed out that recurrences are often " false that is they occur beyond the area of the repair which should therefore extend wide of the defective area Furthermore, relief incisions may weaken the abdominal wall. The mesh can be placed next to bowel Only mild adhesions form and the mesh becomes covered with peritoneum on its inner surface

When infection occurs in hernial repair the result depends on the material used. If fascia is used it sloughs out, and silk or cotton causes persistent sinuses, but if tantalum is used the wound will heal perfectly providing catgut is used as ligatures and the mesh is fixed with wire. The peritoneum should be closed with braided tantalum as the monofilament suture tends to cut out. The material may be used in sheets for the repair of large lumbar hernias. Lattimore and Koontz (1954) stated that serum often collects in unavoidable dead spaces on and under sheets of mesh which may be as large as a foot square To deal with this, aspiration and drains are messy so they now use two catheters on each side, with many holes in them, one being attached to suction The catheters are shortened in 3 days and removed on the fourth. Tantalum mesh may be used in the treatment of difficult inguinal hernias, as a reinforcing layer Burnell (1954) reported the case of a man who died from an unrelated gastric haemorrhage 12 days after the repair of an

inguinal hernia. The mesh could only be removed forcibly and then in because of the permeation of the mesh by tissue ingrowth He cautioned the use of a combination of metals because of differences in electrical po which may lead to a colliquative necrosis.

Tantalum failures—Koontz (1955) reported 139 large ventral hernias were operated on in the previous 7 years and in which tantalum gauze was He drew attention to " false hernias occurring at the edge of the mesh wh is too small and advised that relief incisions should not be made in are covered by muscle. He made the valuable suggestion that big hernias trea gauze may be cured at a second stage procedure when, owing to impregnat the mesh by fibrous a strong tissue has been produced for overlap

Nylon mesh

This substance has been used for the same purpose as tantalum. It can be and produces no untoward effects. It is easy to work with.

Stock (1954) uses it in the repair of large hernias. The material is ch because of its commercial use, than tantalum, which has no such use treatment of ventral hernia the material is placed between peritoneum and m There is no sepsis or delayed healing. There is some induration and tend round the wound for a week

Fortisan fabric

Narat and Khedroo (1952) gave a detailed description of this materia compared it to tantalum mesh. Of the latter it is stated that after a year mentation due to fatigue occurs. This causes no weakening but unpl sensations may occur owing to the broken pieces. If it is very near the cardboard effect may occur and lumps may be caused by bending of the A slough may develop if the skin is sutured directly over the mesh The au cited stated that Fortisan is a regenerated cellulose yarn produced by orienting the internal filament structure of cellulose acetate or other cellulose yarn and saponifying it, that is splitting of combined acid radicals. These c tions result in a fibre of great strength, resistance to stretch and dimen stability under the influence of humidity and wetness. Experimentally Fo is shown to be pliable, causes minimal tissue reaction, and possesses greater t strength than silk or cotton.

Fortisan fabric 5157 is the material used. It is sutured in place with br Fortisan thread size D Experiments on dogs, using different materials and segments of the rectus muscle and its sheath had been removed, showed essen similar results with Fortisan as with tantalum. Both materials were well integ into adjacent tissues and were practically inseparable from them. Using Fo fabric the occasional unpleasant effects encountered when using tantalum avoided Koontz and Kimberley (1954) expressed their great satisfaction tantalum mesh having used it for 8 years for large defects with poor surrou tissues It is superior to all other fabrics and cracks or breaks have no signific as by then the fibrous tissue for which the mesh acts as a scaffolding has taken and the mesh has fulfilled its purpose. In the search for a still better ma they used Fortisan fabric experimentally in dogs. In infected wounds this f lay rolled up in an abscess cavity or caused a buried granuloma or infected

track. They express doubts of what the results would be if Fortisan were used in humans with large hernias and poor tissues

Polyvinyl sponge

Grindlay and Clagett (1949) described a recently developed plastic sponge—Ivalon. It is derived from formalinized polyvinyl alcohol. It causes no inflammation and in canine experiments in which a lung had been removed the sponge cut to the size of the pleural cavity was placed in the thorax. The post-operative course was uneventful. When 3 months later, the dogs were sacrificed the plastic was found to be covered by a layer of avascular collagenous fibrous tissue and pleural membrane, adherent to the chest wall. Histologically there was a minimal inflammatory reaction in the sponge and its fibrous capsule. The interstices of the sponge were lined by a single layer of tissue resembling vascular endothelium. Schofield (1955) discussing fabrics for hernial defect repair considered that polyvinyl alcohol sponge comes even nearer the ideal than does tantalum. High quality sponge is made in England.* It is of uniform texture, white, with a cut surface like that of a slice of bread. When dry it is extremely light, hard and rigid. When moist it is soft and resilient, cuts easily and takes a needle readily. Physically it has a great affinity for water. Temperatures up to 120° C have no effect on it but after an hour at 160° C it turns brown. It shrinks slightly on the first boiling, but not on any subsequent ones. If it is compressed while in water above 95° C and if the compression is maintained while the sponge is cooled to a temperature below 95° C, it retains the deformity produced by the compression. If stored dry it keeps perfectly. If it is exposed to air when moist, fungus and rust may infect the interstices and cause dark stains. For use it is cut in slices 3 to 4 millimetres thick and boiled for 20 minutes in sterile water. It should float freely as contact may deform it. It is either allowed to cool before use or is put in cold sterile water. Schofield, Hallenbeck, Grindlay and Baldes (1954) tested the tensile strength and obtained sound repairs in experimental defects in animals. The sponge is cut to size and sutured in position preferably between two layers of tissue. It is sutured in place with silk or linen. There should be no movement at the edges as, if the sponge gets loose, it will become encapsulated rather than incorporated in the tissues. Granulation tissue invades the interstices of the sponge and provides a semi rigid framework. As the granulation tissue matures to fibrous tissue the repair becomes solid but not rigid. There is an almost complete absence of foreign body reaction. Nevertheless, infection is a danger in the use of any foreign material and must be guarded against. When the sponge was placed in contact with the abdominal contents the surface was peritonealized within a few days and there were no adhesions between small bowel and omentum and the sponge. Skin of paper thickness over the sponge may slough and therefore fascia or other tissue should be interposed. Haemostasis should be absolute and drainage is not used. The sponge stretches on movement. The patient remains in bed till the stitches come out.

Polythene is a more irritant material and does not absorb tissue fluids as does sponge. Zimmerman (1952) considered that, in the treatment of inguinal hernia, the added strength obtained by the use of foreign materials does not offset the hazards and complications of their use.

* Manufactured by the Ramer Chemical Co., 79 Blackheath Road, London, England.

Summary

In the treatment of hernia of any type where the canal or abdominal wall needs strengthening, steel wire has given excellent results, and in cases where additional reinforcement is necessary tantalum mesh holds pride of place. Polyvinyl may well develop into an important ancillary to strengthen defects in hernial areas or in the abdominal wall.

BILE DUCT PROSTHESES

Numerous materials have been used for prolonged drainage of the common bile duct. The substance most commonly used has been rubber. Cole, Ireneus, and Reynolds (1955) agreed with the findings of Lary and Scheibe (1952) who showed that when a prosthesis is left in the common bile duct for a long time inflammation and scarring of the duct occurs. Pearse (1955) has reviewed the matter and his observations follow. He quoted Cattell (1947) to the effect that "the type of material over which the repair is performed is not as important as the way in which the procedure is carried out," and Walters (1953) who stated that "no matter whether the tube used as a splint is made of natural or synthetic rubber, polyvinyl material or vitallium, if it is left within the duct long enough bile pigment will accumulate in its lumen and around its sides and varying degrees of obstruction and infection will be produced." Vitallium used as a bile duct prosthesis has the advantages of being smooth and lacking in tissue reactions. It also has a high tensile strength and can be made with a large lumen and a very thin wall. Tantalum *reacts in much the same way but cannot be welded to attach a flange for anchorage.* Plastics have the disadvantages of causing local irritation and polythene, though less irritating, cannot be made into the necessary shape in a single piece. The hardness of Vitallium makes its shape unalterable at operation, and its removal is only possible by operation. The first Vitallium tube was inserted in February 1940. In December 1952, owing to common duct obstruction of a few months standing, a further operation was undertaken. The Vitallium tube was found to be blocked with black concretions and was lying free in a dilated duct.

In 1946 Pearse made a follow up study 5 years after the method of use had been published. Of the patients 11.3 per cent had experienced difficulty with the tubes, which were plugged with cholesterin, calcium and bile pigment. In patients with early obstruction symptoms were benefited by the use of sodium *taurocholate or* dehydrocholate. These drugs were considered to act by dissolving the cholesterol fraction and releasing the insoluble sediment, thus re-establishing bile flow. Pearse believed that a Vitallium bile duct tube has served its purpose after a year and should then be removed. This is in accord with the general opinion that foreign bodies when used in the bile duct should be removed at some time not longer than a year after their insertion.

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CHAPTER 8

DENTAL SURGERY

G A MORRANT

INTRODUCTION

IN DENTAL SURGERY the purely surgical procedures have always formed only a proportion of the work of the dentist. Much of his time is spent in restoring the function and aesthetic form of the natural teeth and following surgery in replacing lost tissues by artificial substitutes which must be compatible with the intricate function of the masticatory apparatus. In these operations concerned with the repair or replacement of tooth structure the manipulation of materials plays a most important part. The ever-extending range of materials resulting from advancing industrial technology is leading to the development of specialized dental techniques, where the properties of these new materials can be utilized in constructing more accurate and aesthetic replacements of both the hard and soft tissues The object of this chapter is to outline some of the materials in common use in dentistry together with recent developments, to give a brief description of the manipulation of these materials and their properties, and to indicate the type of situation where they are applied It is possible that some of the information may be of use in solving problems in other fields of surgery

IMPRESSION MATERIALS

It is convenient to start with this group of materials since frequently before any treatment is commenced it may be necessary to take an impression in order to obtain a model of the mouth for study and the planning of treatment. A model is also an essential preliminary in the construction of any prosthetic or orthodontic appliance In the restorative field, too a model is often required of the prepared tooth cavity or crown so that an inlay or jacket crown may be made in the laboratory

Plaster of Paris

A material still widely used in dentistry for impressions is plaster of Paris, particularly in the case of the edentulous mouth where there are no undercuts to prevent the withdrawal of a rigid substance. Impression plaster normally has incorporated in it modifiers to regulate the setting time and to control its otherwise high setting expansion.

A plaster impression is treated with a separating medium before the model material is poured into the impression. The model material is most often again plaster of Paris, but if a harder and stronger model is required, an alternative form called dental "stone" is used.

Dental impression compound

Another substance perhaps even more widely used than plaster for taking impressions is dental impression compound, which may be used alone or in con junction with another impression material used as a wash over the compound Plaster the elastic materials (*see* below) and an impression paste consisting basically of zinc oxide and eugenol are frequently used in this way

One of the special uses of compound is the taking of an impression of a cavity or a prepared stump of an individual tooth for which a gold inlay or some form of crown is to be constructed A copper ring of correct size to fit over the tooth is used to contain the compound Although this technique for inlays is being supplanted by the use of plastic materials it is still the usual method for jacket crown impressions The impression surface is now often copper plated and backed by dental stone to form a model (Rosenstiel, 1950) This is extremely accurate and has a very hard surface upon which the crown or inlay can be finished

Elastic impression materials

However none of these materials has ever really satisfactorily solved the problem of taking a completely accurate impression of the mouth in one piece where the teeth are standing because where there are teeth there are almost invariably undercuts In the case of plaster the mass can be allowed to set around the teeth and can then be removed from the undercuts by fracturing. The impression is re formed by subsequent piecing together of the various parts prior to pouring the model. The technique with impression compound is to remove the material before it has completely hardened The compound will usually drag away from the undercuts without too great a distortion but for real accuracy an exacting sectional method has to be employed The advent of the various types of elastic impression materials during the last twenty years has immeasurably eased the lot of the dental surgeon and patient.

Agar hydrocolloids

A hydrocolloid based on agar agar was the first of these to be developed and is still widely used for crown and bridge work, which requires precision and great accuracy of reproduction The agar is compounded with kaolin or other fillers, with the addition of glycerin and potassium sulphate. The properties of the resulting gel will depend largely on the type and proportion of the agar and the precise method of making up the hydrocolloid Its use in dentistry depends on its liquefaction temperature being greater than its gelation temperature In practice, the material is boiled in a tube or special syringe until it liquefies. This can then be stored in a water bath at 63 C. for the whole day where it will remain liquid ready for use. This material is often injected directly into the tooth cavity from a small syringe prior to the placing of the full impression tray of hydrocolloid. The mass is then thoroughly chilled for 3 to 5 minutes before removal. The resulting impression is somewhat rubbery in consistency but is liable to tear easily The surface is smooth and reproduces fine detail well The main disadvantage of this type of hydrocolloid impression material, apart from the special equipment

required is its lack of dimensional stability owing to the exudate which rapidly forms on the surface of the impression after removal from the mouth. Even an atmosphere of 100 per cent humidity does not entirely arrest the process, whilst immersion in water results in a swelling of the mass. The model from a reversible hydrocolloid impression should therefore be poured within a few minutes for maximum accuracy

Irreversible hydrocolloids

The agar hydrocolloids are termed reversible in that the gel can be turned into a sol by heat and back again to a gel by cooling. With the advent of World War II supplies of agar for dental hydrocolloid ceased and this hastened the development of an irreversible hydrocolloid based on a soluble alginate. This forms a viscous sol when dissolved in water but can be turned into an insoluble gel by a chemical reaction This gel cannot be returned to the sol stage. In a typical dental impression material, sodium alginate is compounded with calcium sulphate the main reactor and suitable fillers together with a retarding salt such as trisodium phosphate

In use, a carefully proportioned amount of alginate powder is added to the appropriate quantity of water in a mixing bowl and spatulated to a fairly stiff paste. During this phase and while the material is being loaded into the impression tray and placed in the mouth the calcium sulphate reacts preferentially with the sodium phosphate. When this added salt is used up the remaining calcium sulphate continues the reaction with the sodium alginate to form insoluble calcium alginate. The alginate impression materials set in the mouth in about three minutes, but the temperature of the mixing water has an appreciable effect on the gelation time. The alginates form very similar impressions in feel and consistency to the agar type materials but are probably somewhat tougher They have been improved greatly during the past 5 years by various modifications in their composition, and while at one time it was considered that they were not quite as accurate as the reversible hydrocolloids for reproducing individual tooth preparations for bridge work, it is now thought that they can be regarded as equally satisfactory However like the reversible hydrocolloids, the alginate gels are dimensionally unstable. Therefore, as before, the model must be poured as soon as possible. Recent work (Morrant and Elphicke, 1956) has shown that liquid paraffin *B.P* appears to be a medium in which alginate impressions may be stored for up to 24 hours with minimal dimensional change.

Synthetic elastomers

The problem of post impression dimensional stability and the possibility of incomplete recovery of hydrocolloid materials after withdrawal from severe undercuts, especially in the field of restorative dentistry has led in the last 4 years to the adaptation for dental techniques of two commercial synthetic elastomers, the first being based on a polymerizable mercaptan commercially known as Thiokol, the more recent being a silicone rubber

The Thiokol base is marketed by a number of dental supply companies under their own proprietary brand names and is generally referred to as " rubber base " impression material (Skinner and Cooper 1955) It is dispensed as a paste in a tube and requires a catalyst or accelerator to bring about polymerization The principle ingredient of the accelerator also made up into a paste is lead peroxide and the two pastes are then mixed together on a glass slab in the same way as the zinc oxide and eugenol pastes already described. The material is stiff extremely sticky and more difficult to mix, especially in larger quantities. It is, therefore

normally used with ordinary dental impression compound as a lining impression similar to the plaster wash or by itself in a small perforated tray or band for taking impressions of individual teeth The catalysed material normally sets in the mouth in about 5 minutes but it appears unduly sensitive to environmental temperature and humidity during mixing, an increase in either of these reducing the setting time There appears to be no significant contraction on polymerization and with correct technique perfect accuracy of reproduction is obtainable The final impression is very much tougher and more resilient than the hydrocolloid materials, being similar to true rubber It seems to remain completely stable in every way over a period of weeks and even months. Unlike impression compound it does not copper plate easily The main disadvantages of this substance would seem to be its expense, unpleasant smell and difficulty of handling before setting due to its stickiness. Smears of the material on skin and instruments are difficult to remove

More recently " cold vulcanizing silicone rubbers have been introduced for dental use Like rubber base " materials the basic substance is presented as a paste in a tube, but the catalyst may be made up as a liquid The paste probably consists of partially polymerized polydimethylsiloxane with zinc oxide for a filler The catalyst is probably an ethyl silicate containing an accelerator such as dibutyl tin dilaurate Manipulation and clinical technique is similar to that for rubber base but the silicone material is not so sticky in handling and has a pleasant smell The silicone materials polymerize more rapidly and there is thus less time for manipulation Accuracy elasticity and toughness of the resulting impression are probably greater than with Thiokol rubbers There is a very slight shrinkage which takes place in the impression probably due to continued slight polymerization However this is not greatly significant, particularly if the material is retained in a perforated metal tray The clinical results show equal accuracy to the rubber base " materials. The original silicone rubbers formed hydrogen gas when in contact with the moist plaster or stone poured into the impression and this resulted in a porous model Recently modification of the catalyst appears to have overcome this problem Unlike the Thiokol synthetic rubber the silicone rubber accepts a film of deposited copper fairly rapidly It is probable that in time the silicone rubbers will replace the Thiokol type

DENTURE MATERIALS

In denture construction a replica of the denture is made in wax with the artificial teeth set in the correct position. This is then placed in plaster in one half of a metal flask leaving one of the surfaces exposed After application of a separating medium the second half of the flask is filled with plaster and the two parts placed together The flask is heated to melt the wax and is then separated once more to reveal a two-part mould cavity the shape of the wax denture with the teeth being retained in position in the plaster

The commercial development of polymethyl methacrylate a clear resin commonly known as Perspex, has led to its use in denture construction as seemingly an almost ideal material. It is chemically and colour stable light in weight, translucent and yet easily tinted reasonably hard and strong, and heat stable up to 125 C when it begins to soften. In addition it is comparatively easy to process

requiring no special apparatus The cessation of rubber supplies during World War II made its adoption virtually obligatory and universal.

Although a thermoplastic resin it is not moulded in dentistry by this method but, as with many other dental materials, is presented as a liquid and a powder actually the monomer and polymer forms. The monomer is pure methyl methacrylate usually with a trace of hydroquinone inhibitor to prevent polymerization during storage The polymer powder consists of fine granules of polymethyl methacrylate but is sometimes a co-polymer with some other resin. The polymer granules carry the pigment A small quantity of a plasticizer such as butyl phthalate, is also incorporated in the polymer together with a trace of benzoyl peroxide

The function of the monomer is to form with the polymer a plastic mass suitable for packing into the mould. Since monomer on polymerization exhibits a contraction, the quantity is kept to a minimum, but must be sufficient to wet all the granules. In practice the monomer is proportioned and polymer added until all the monomer is taken up The monomer then attacks the polymer granules, which become tacky The mass appears stringy if pulled apart. The mixture gradually changes into a smooth dough, in which stage it is packed into the denture mould. If this is not done, the mass proceeds to become tough, rubbery and unworkable, proceeding gradually to complete hardening. The mixture is ready for packing into the mould in about 15 minutes, depending on the type of polymer the monomer-polymer ratio and the temperature of the mixing vessel.

Prior to packing the acrylic the mould must be lined in order to prevent access of moisture to the resin during processing, which would affect the colour of the resin and cause subsequent crazing. Tin-foil or a coating of alginate is used for this purpose and also serves to prevent adhesion to the investing plaster After a trial closure of the two parts of the flask with separating sheets of cellophane, it is finally closed and placed in a clamp under strong spring pressure.

The polymerization reaction is initiated by the breakdown of the benzoyl peroxide to form free radicles. This is brought about by heat, usually applied by immersion in a water bath at 60°–70° C., which will effect "curing" in about 9 hours. Owing to the exothermic nature of the polymerization reaction, the internal temperature of the thicker parts of the denture may be increased above the temperature of the water bath. If the internal temperature is sufficiently high, monomer will boil before polymerization takes place, producing porosity in the finished product. Much work has been done in finding the best temperature cycle for curing both thick and thin portions of the denture and the tendency is now to give longer curing times, finishing off with 30 minutes in boiling water

The monomer–polymer mixture contracts in volume during processing and this may produce actual contraction away from the palate in the upper denture or merely stresses in the thinner palatal portion predisposing to fracture in this area Acrylic resin dentures absorb water swelling slightly in the process. This is complete in about one week at body temperature However in practice the expansion does not compensate for curing shrinkage The denture resins are virtually insoluble in the oral fluids

Following the development of acrylic resin as a tooth-filling material (see below) a number of cold cure "self-curing or "auto-polymerizing denture resins have been recently developed

Instead of using heat to activate the benzoyl peroxide a small amount of a chemical activator is employed. This is usually a tertiary amine, such as dimethyl-p-toluidine added to the monomer The curing takes about 30 minutes, but polymerization is never as complete as with heat-cured resins, and the longer they can be left before

deflasking the better They have not been widely adopted for routine use because they show slightly less strength and exhibit greater shrinkage and distortion The material has been found useful for quick repairs and as special impression trays and bases in certain clinical techniques. It was at one time advocated that an impression could be taken in the material and made an integral part of the subsequent denture. However burns of the oral mucosa from monomer and the exothermic reaction were recorded on occasions and the technique has been abandoned

There has been considerable discussion as to so-called sensitivity or allergy to acrylic resin dentures (Smith and Bains 1955) Some authorities think that, if it occurs, it is due to an improperly processed denture Others suggest that any signs or symptoms ascribed to this cause are usually due to errors of fit or occlusion

Recently nylon has been introduced as a denture base material and has a number of properties which would seem to make it an improvement over acrylic resin Its great strength combined with its flexibility enables it to resist shock and repeated stressing and also makes it possible to fabricate skeleton design partial dentures in the material It is lighter in weight than methyl methacrylate and also extremely tough and resistant to abrasion However the material has to be injection moulded at a relatively high temperature which should be carefully controlled This necessitates more complicated equipment than is the case with acrylic resin but small injection moulding presses suitable for the dental laboratory, are available Associated with this processing technique there is a high mould shrinkage and reports so far available have commented on the warpage and lack of dimensional stability resulting in a poorer initial fit than is possible with acrylic (Matthews and Smith 1955) Nylon is also more difficult to finish and polish and does not retain its surface as well as acrylic having also a higher water sorption (Watt 1955) Reports have mentioned that a natural colour is more difficult to obtain than with acrylic resin and is also subject to deterioration. In processing there is, of course, no physical union with the teeth whether porcelain or acrylic. The flexibility and lack of rigidity of the material may be of help in certain designs of denture but a very distinct disadvantage in others.

The teeth on artificial dentures, until the advent of acrylic resin were always made of porcelain Although lifelike teeth in acrylic are made more economically they have by no means completely replaced porcelain In spite of the use of co-polymers and the advantages of industrial processing methods the hardness of acrylic teeth remains low compared with natural or porcelain teeth and they often show more abrasion

Metals in denture prosthesis

Since World War II the popularity of chrome-cobalt alloys for partial dentures has been growing These alloys were originally developed for dental use but now have applications from bone surgery to jet engine components They are lighter stronger and harder than gold alloys and more corrosion resistant than the " white golds " but they have much less ductility allowing of less adjustment in the mouth and thus requiring a more accurate clinical and laboratory technique Tissue tolerance is excellent The chief obstacle to their wider use has been the complexity of the laboratory procedures and apparatus, virtually limiting chrome alloy denture fabrication to large commercial or hospital laboratories But the

extended range of these alloys developed during the war has increased the dental availability of the material and there are now a larger number of laboratories undertaking this type of work The same basic casting technique is used as with gold, but the high fusion temperatures of the alloys (about 1,300° C.) necessitates a stronger investment binder than plaster The investment may be mixed with ethyl silicate, which forms a silica gel initially fusing in the higher temperature range. Then, too melting the alloy requires the use of an oxyacetylene blow torch or an electric induction casting apparatus and a furnace capable of pre-heating the mould to 1 100° C. The investment adheres strongly to the casting and a sand blasting unit is normally used for preliminary finishing. Owing to the extreme hardness of the metal, high-speed electric motors or air turbine hand pieces are employed in smoothing and polishing the denture. To reduce the amount of laborious finishing required investing is performed with prolonged electrical vibration to eliminate air bubbles.

Implants

A recent application of the chrome cobalt casting has been in the construction of subperiosteal dental implants (Mack, 1955) The stability of a full denture or partial denture where one end is not resting on teeth is often a considerable problem The technique is being tried of fabricating a stump in metal arising from a framework made to fit the underlying bone, in order to provide a firm rest for the denture. Briefly the procedure is to lift a flap of mucosa and periosteum and take an impression of the bone surface. After construction of the implant on the resulting model the wound is reopened and the implant fitted to the bone. The soft tissue is then replaced over the base and sutured around the neck of the stump which is allowed to protrude through the mucosa. There remains, of course, in theory a passage for infection straight through to the underlying bone. However the implant seems to become firmly held in place by fibrous tissue and so tight is the adaptation around the neck of the stump that in practice failure from infection does not seem to occur The difficulty of adapting and opposing the flaps over the bulk of the implant seems to be the greater problem, and the technique is still in an experimental stage

TOOTH RESTORATIVE MATERIALS

Since the problem of combining strength and good appearance in the repair of tooth structure is one that has not been completely solved, restorative materials tend to fall into two groups. The metallic materials are unaesthetic and are usually confined to the posterior teeth, whilst anterior crowns and fillings tend to consist of ceramic or plastic substances.

Amalgam and gold

In spite of recent experiments with gallium alloy (Smith Caul and Sweeney 1956) amalgam shows no sign of being replaced as the most frequently used restorative material. Alloys continue to improve in composition and manipulative qualities, whilst recently developed aids such as mechanical mixers and packers, are becoming more widely adopted.

Advances in gold inlay technique and bridgework have centred around the

development of elastic impression materials and improvements in investing and casting methods rather than in the gold alloys themselves Investing wax inlay patterns under vacuum has eliminated surface imperfections and improved the fit of gold castings.

Materials for anterior teeth

Silicate cement

Silicate cement, sometimes called synthetic porcelain can produce, under favourable conditions restorations which are very pleasing initially but unfortunately they deteriorate in time owing to the slight solubility of the cement The filling also wears away and becomes stained Another disadvantage is its brittleness, which makes it unsatisfactory for restoring the incisal edges of teeth In spite of these disadvantages there appears little prospect of improvement in the actual material

Fused porcelain

Porcelain itself has similarly been in use for many years for the construction of jacket crowns and inlays which are excellent aesthetic matches of the natural teeth, although the inlays always show a cement junction line The disadvantages of the material lie in the difficulties of its technique and its brittleness, which renders porcelain crowns rather liable to fracture However recent improvements in low fusing porcelain powders and electric furnaces with base metal elements have eliminated the need for the expensive platinum-wire furnace

The firing of porcelain under vacuum has been introduced, both for factory made denture teeth and for individual crowns fabricated in dental laboratories The process is speeded up and porosity is reduced, leading to a more aesthetic final result.

Acrylic resin

The advent of acrylic resin was hailed as the material to solve all the problems in the restorative field, since lifelike crowns and so on could so easily be fabricated in the dental surgeon's own laboratory However it was soon found that some tooth shades were hard to reproduce and match consistently and that in some cases the shades were not colour stable. The material as mentioned previously also exhibits a curing shrinkage which is of considerable significance in the finer limits of restorative work But its main disadvantage lies in the water sorption and high coefficient of thermal expansion which, with the resiliency of the material, tends to break the cementing medium securing the crown or inlay in place Add to this the poor abrasive resistance and it will be seen that heat-cured acrylic resins have severe limitations in their use for tooth restoration. Correct processing may minimize the defects and the material has advantages in certain situations but the tendency is to return to greater use of porcelain where possible.

Chemically activated acrylic resins

The development of self-curing or chemically activated acrylic resins as filling materials has been one of the biggest advances in restorative dentistry since World War II Two problems have had to be solved the speeding up of the polymerization time without the application of heat and the compensation for

polymerization contraction without employing heavy pressure. The acrylic polymers have had to be carefully modified for the polymer structure closely affects manipulation characteristics, including the time of the reaction. Three systems of chemical activation are in current use and have been developed largely in the quest for colour stability (Morrant, 1956). The original system of a tertiary amine in the monomer reacting with benzoyl peroxide on the polymer produced severe amber discoloration and, although this system is still the basis of a number of brands of the material, it has been improved by the use of purer activators and the inclusion of stabilizers. *p*-Toluene sulphinic acid is the activator used in one brand of acrylic resin and has been found able to initiate polymerization without the aid of other substances. This resin has discoloured under certain circumstances and another system of activation based on lauryl mercaptan and benzoyl peroxide has been the latest development. It is to date proving satisfactorily stable.

The compensation for polymerization contraction has been obtained by the use of a variety of techniques, all attempting to direct the inevitable shrinkage towards the walls of the cavity and has included the use of various bonding agents. However, the high coefficient of thermal expansion of acrylic (seven times that of tooth structure) tends to break any adhesion to the tooth cavity after a while and percolation around the filling is possible, leading to staining at the edge and possibly to recurrent dental caries. While not as brittle in incisal restorations as silicate cement, nevertheless it exhibits wear and, although it has a number of advantages over silicate, it is clear that the ideal filling material has not yet been produced.

Epoxy resins

Experiments which have been undertaken with epoxy resins (Bowen, 1956) indicate that they can be formulated with suitable fillers to provide a material eliminating some of the undesirable properties of methyl methacrylate.

Apart from the possibility of a better filling material, the development of an adhesive plastic forming a permanent bond to tooth structure could have great possibilities as a caries preventive. Many carious lesions begin in the enamel fissures on the biting surfaces of the posterior teeth. The occluding of these fissures without operative interference would be a very significant advance.

Cavity linings

Of recent years there has been considerable discussion of the effect on the dental pulp of the various filling materials. To prevent pain due to thermal stimulus it has long been correct practice to place a lining of dental cement under the larger amalgam restorations. But a greater problem is the toxic effect of silicate cement and self-curing resins. Silicate cement, a gel structure, appears able, under certain circumstances, to kill pulps over a period of time without pain, particularly in the young person (Zander, 1946). The monomer of self-curing acrylic resins has a similar, although slightly less acute, inflammatory effect (Kramer, 1956) and it is now considered that cavities for both these materials should be lined.

The cement normally used for this purpose and for cementing crowns and inlays is supplied again as a powder and liquid. The powder is largely zinc oxide and the liquid is similar to that used with silicate cement powder, phosphoric

acid In this case the final product a zinc phosphate is a crystalline structure but is also capable of producing some inflammatory reaction in the pulp probably due to acid present before the cement sets However this is not usually of any very great clinical significance

Zinc oxide and eugenol has long been used as a temporary cement or bland dressing for an inflamed pulp A number of brands of accelerated zinc oxide and eugenol cement are now available for cavity lining based probably on the use of zinc acetate or acetic acid as an accelerator These cements are not so smooth and easy to handle as the zinc phosphate type, nor are they as strong. Unfortunately they cannot be used directly under acrylic resin restorations owing to plasticization of the acrylic by the eugenol

Brief mention may be made of the technique of root canal therapy the advisability of which has in the past, been hotly debated It is now generally recognized that, properly executed it has its place in the preservation of the teeth and that a perfectly normal peri apical radiographic appearance may be re-established in successful cases A factor in such success is the proper mechanical enlarging and rendering sterile of the pulp canal in the root. The use of antibiotic pastes has been of great assistance in attaining this. Root canals are then subsequently filled to prevent reinfection and allow healing at the apex. The usual method is to occlude the canal with a tapered gutta percha point. These are now made in graduated sizes to correspond to the size of the enlarging instrument but an inert sealer is employed in addition This is usually zinc phosphate or a cement based on zinc oxide and eugenol

INSTRUMENTATION

The process of cutting hard dental tissues even if pain is eliminated by local anaesthesia is trying for both operator and patient trying for the operator because of the comparative slowness of cutting very hard tissues in an often obscured field with the danger of overheating the dental pulp trying to the patient again because of the slowness of the operation but perhaps even more because of vibration and bone conducted noise.

The introduction of dental burs with tungsten carbide heads, which are now widely used, has resulted in quicker and more efficient cutting of enamel and dentine compared with the ordinary steel bur but more care has to be exercised with them owing to their brittleness (Lammie, 1953) Dental chisels and scalers also are now being supplied with tungsten carbide tips

An attempt to eliminate the noise and vibration of drilling was the development of the "airbrasive" technique in which tooth structure was sand blasted away by particles of aluminium oxide carried on a propellant of carbon dioxide (Myers 1954) The method was also tried for cleaning teeth using a less abrasive material. Although very well tolerated by the patient, the technique has not been widely adopted owing to the many operative difficulties These include lack of the usual tactile sense while cutting, the need for exceptional visibility the necessity for protecting other teeth and problems concerned with the dust control.

Another method employing an abrasive which is at present the subject of clinical trial is the adaptation of the commercial ultrasonic drilling process (Oman and Applebaum 1955) Here an abrasive slurry is interposed between the tooth and a

tool vibrating at ultrasonic frequencies This method like the airbrasive technique, is well tolerated by patients it being reported that pain is considerably reduced. However the technique is comparatively slow and there are a number of other difficulties to be overcome by the operator in particular the obscuring of the operating field by the abrasive slurry during actual cutting. It is doubtful whether the use of this method of cavity preparation will ever become widespread.

With the more conventional operating methods the trend has been towards the employment of higher speeds combined with greater use of diamond impregnated points for cutting dental enamel These require a cooling jet of air or water or atomized combination, which ideally is discharged from a tube fixed to the dental handpiece and is directed on to the cutting point. Engines and transmission systems are now being made to operate handpieces up to 30 000 r p m. This has necessitated the development of dental handpieces with improved bearings such as sapphire or ball bearings. Most of the new stainless steel handpieces can very quickly be dismantled completely for sterilization Turbine handpieces have now passed the experimental stage and are available One type is driven by water which is pumped down a flexible tube to the handpiece Here it drives a rotor surrounding the bur chuck at 45 000 r p.m . Special diamond points are used with this instrument. A compressed air turbine handpiece has been produced with manual spring control on the handpiece itself giving speeds up to 50 000 r p m. This uses standard dental cutting points and works through a small turbine motor attached to one end rotating at 140 000 r p.m The handpiece itself is driven through a reduction gearing to obtain greater power A new specialized belt transmission system, which is taken down into the handpiece where it is taken round the bur chuck itself produces speeds up to 200 000 r p m (Kilpatrick, 1956) but requires special carbide burs and diamond points. The latest development in the realm of high-speed cutting is the use of an air turbine handpiece similar in construction to the water turbine type with the rotor in the head of the handpiece. This works normally in the speed range of 250 000 r p m. but has very low power However at these high speeds very little pressure is required to cut tooth structure The development of higher speeds was based originally on the greater efficiency of diamond abrasive tools when cutting at a high peripheral speed but it is now found that small carbide burs are also very effective in the highest speed range Coarse vibrations tend to be smoothed out at high speed and the vibration frequency may become above patient perception. All this provides speedier and more comfortable operating for both patient and dental surgeon Numerous variations on the theme of high speed are being developed, with the result that the approach to cavity preparation methods is undergoing rapid change.

MISCELLANEOUS MATERIALS

There remain a large number of appliances and techniques, notably in the specialized branches of dentistry of which space does not permit a description Basically they involve the materials and procedures already described However mention may be made of the large range of stainless steel wire, tube and tape used in constructing orthodontic appliances and which occasionally has application in other special dental techniques The various components of the orthodontic appliance are normally joined together by spot welding.

Physical haemostatic agents

There is one other class of materials which it may be of interest to note although they might be considered to fall within the realm of pharmacology The use of physical agents for haemostasis and for better healing after dental extractions has been a comparatively new development and although they are not yet very widely employed a fair amount of research has been undertaken into their properties Three materials are in common use

Oxidized cellulose

The first is oxidized cellulose, formed by controlled oxidation of cellulose by NO_2 This preserves the physical form of the gauze or wool although it remains somewhat friable. The material is sterilized by chemical means The haemostatic effect is probably due to its slightly acidic nature to the swelling which occurs when it is introduced into the wound and possibly to the formation of coagula consisting of salts of oxidized cellulose and haemoglobin The material is slowly absorbed as it becomes incorporated into the organizing blood clot

Gelatin sponge

A similar type of material is gelatin sponge, prepared by converting gelatin usually soluble, into an insoluble but absorbable material Gelatin sponge is less liable to disintegrate in application than oxidized cellulose Although gelatin is often combined with thrombin this is not necessary for most oral surgery procedures, the sponge having sufficient haemostatic properties of its own It probably acts by forming a matrix to support the blood clot. It is compatible with penicillin

Sodium and calcium alginate gauze

The third type of material in common use as a haemostatic agent is wool or gauze composed of sodium and calcium alginate Sodium alginate dissolves in water which, when acted upon by ionic calcium, undergoes instantaneous coagulation Clinically it is found that sodium alginate in contact with blood and tissue exudates forms an artificial clot because of the reaction of the calcium ions present. However the haemostatic effect is slow and unreliable and the sodium alginate is usually combined with the insoluble calcium alginate which probably adds to the haemostatic effect by giving physical support to the clot. The material exhibits no inhibitory effect on penicillin streptomycin or the sulphonamides and is easily absorbed

A comparative study (Kruger 1954) of these three materials has shown that oxidized cellulose and gelatin sponge are effective haemostatic agents, reducing post-operative pain and not retarding healing. Calcium-sodium alginate wool, on the contrary was not found effective for haemostasis and tended to *increase* post-operative pain with delay in healing.

In dental operations involving resection of gingival tissue a haemostatic and protective pack is usually placed over the raw areas and kept in place by attachment to the teeth A zinc oxide-eugenol type of material is usually employed with the incorporation of asbestos wool or similar substance to give body and cohesion to the mass

CONCLUSION

This chapter has been an attempt to describe the present position in a field where materials and their associated techniques play a particularly large part in the treatment of the patient, and where like other branches of surgery the past few years have seen many developments Some will turn out to be merely experiments in the long quest for better treatment Others will no doubt be incorporated into the pattern and practice of everyday dentistry as it advances from being regarded as an occasional evil necessity to being thought of as an essential factor in the maintenance of general health

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CHAPTER 9

NEUROSURGERY

HARVEY JACKSON

CHOICE OF MATERIALS

IN THE CHOICE of materials a number of important factors have to be considered These include the nature of the substance, the condition of the patient the expediency of the procedure and the circumstances of the undertaking

Where the replacement of structures is necessary not only should stress be put on the use of human tissue whenever possible but that the source should be autogenous. Unfortunately it is never possible to be certain of the permanency of the result where extraneous materials are introduced even though years may elapse before the failure is apparent. Nevertheless, these materials must of necessity be used from time to time. Any substance that has to be buried or retained or both, must be readily sterilizable, non irritant, and should not prejudice subsequent treatment. In referring to the absence of irritant properties both the chemical and the physical characteristics have to be considered Where a supportive function is implied the material must be strong durable and readily retainable *in situ* Should a metallic preparation be contemplated the questions of heat conduction and penetrability or otherwise to x rays must be kept in mind The available supply is a further consideration more especially when donor human tissues are used

CONTROL OF HAEMORRHAGE

In neurosurgery special considerations in the control of haemorrhage arise from the anatomical sites involved, and from the vital functions of the structures adjacent to the source of the bleeding.

Blood coagulation

The normal coagulation of blood involves chemical, physical and thermal agents. The coagulant, thrombin and the formation of an expansive surface as produced by the fibrin network, are of importance

First heat encourages coagulation both by expediting the chemical changes involved in both thrombin production and fibrin formation In greater intensity heat causes direct coagulation of proteins From the early days of surgery heat has been applied, at one time as hot pitch and at the present time as a hot pack The actual cautery is a time-honoured means of controlling haemorrhage though the manner of its application has become more refined and technically more intricate in the form of electrical diathermy By a searing action diathermy can control a steady ooze where coagulation of tissue is no disadvantage for example over areas of dura mater as when infiltrated by meningioma-en plaque

However even though in the majority of cases bleeding within the skull is of an oozing nature, it is not always possible to apply heat after any fashion, owing to the delicate structures that may be harmed Under these conditions the chemical and physical agents concerned in the coagulation of blood may be employed Possibly the most convenient method is the application of crushed muscle, easily available from the temporal or nuchal musculature In this way thrombokinase and prothrombin as well as the expanse of bare area conducive to coagulation are provided These sources of supply are limited and therefore some supplementary source may be needed and it is reasonable for an assistant to collect muscle from the patient's thigh should this larger quantity prove necessary

During World War II quantities of blood became available for the extraction of fibrin because of unsuitability of the blood for transfusion Thin slices of this fibrin could be employed instead of muscle for application to oozing surfaces. As a refinement of this technique the Medical Research Council introduced a sponge like preparation of fibrin known as fibrin foam This sponge, on steeping in a solution of thrombin proved a potent aid to the control of bleeding. Before application it was soaked in a freshly prepared solution of thrombin excess of fluid being then removed by expression.

Fibrin foam is no longer available but commercially prepared substitutes have been introduced The substitutes are preparations of gelatin Unfortunately they are by no means as effective as the original preparation although there were some qualms about the intense power of coagulation of the latter so potent was it that occasionally the possibility of extending venous thrombosis as a result of its application was suspected

Where blood vessels of larger calibre are responsible for the bleeding some means of compression and/or sealing are necessary for control Coagulation by diathermy will suffice in dealing with many of these sources the diathermy is applied either to the points of haemorrhage or to the vessels in continuity

Ligation

Ligation of the bleeding vessel may prove most satisfactory with certain cerebral vessels The difficulty of approach, however makes ligation of more deeply placed cerebral vessels impossible or impracticable even though various specially designed ligature conveying instruments are available Silk, thread and plastic ligature materials are to be applied in suitable circumstances.

Metal clips

The difficulties of approach and manipulation led Cushing to introduce metal clips for application to such vessels The clips are made of silver or tantalum wire they can be purchased as clips or fashioned as required by pliers specially constructed for the purpose

Subarachnoid haemorrhage

The actual aneurysmal cavity can be packed with muscle or one of the other substances already discussed, although the scope for this procedure is limited. As an alternative when ligation obliteration or clipping is unwise or impossible the attenuated arterial wall can be reinforced and for this purpose either muscle or a fibrin foam substitute can be applied in support. It may even be possible to

strengthen the aneurysmal wall by other means, such as spraying with a solution of some substance that on drying reinforces the wall Whilst procedures of this nature are being investigated no really satisfactory preparation has so far been produced

OPERATIVE TECHNIQUES

There are occasions when the neurosurgeon is faced with immediate closure of a wound owing to unforeseen events, or to the requisite operative intervention proving so extensive a venture, as a one stage affair that undue strain would be put on the patient These circumstances necessitate closure of the wound without completion of the internal requirements

Reopening of the wound at a subsequent stage may prove difficult owing to the reaction in the apposed surfaces, especially if the initial procedure necessitated opening the dura mater

It is possible by interposing a sheet of metal foil or plastic material at the primary closure to prevent adhesion between the deeper extensions of the wound and thereby facilitate the process of re-entry Cellophane polythene or tantalum foil will fulfil the requirements Under the circumstances they are retained on a purely temporary basis Permanent embedding of such materials nevertheless is by no means detrimental, although the use of something capable of being absorbed or organized into the body structure is to be preferred

Various preparations of an absorbable nature have been introduced but they have been constituted of a fibrin base. These fibrino-plastic materials have not proved satisfactory for their consistence poor adaptability and poor resilience do not permit of easy manipulation

Cranio-stenosis

Another indication for interposing something between raw surfaces is the separation of bony margins as a means of preventing reunion In cases of cranio-stenosis when reseparation of the sutures is undertaken it is a wise precaution to wrap the bone edges with polythene film

HYDROCEPHALUS

Both the open and closed" types of hydrocephalus call for measures to eliminate the excessive accumulation of cerebrospinal fluid, and thereby avoid either gross enlargement of the head or gross distension of the ventricular system For the purpose some form of fistulous communication must be fashioned between cavities or surfaces or the secretion of cerebrospinal fluid curtailed

Internal hydrocephalus demands that a communication between the ventricular system and the subarachnoid space should be established where as in external or communicating hydrocephalus the fistulous track must form a communication between the subarachnoid space and a channel of escape beyond the cranium

Internal or obstructive hydrocephalus

Cerebrospinal fluid fistulas are an infrequent occurrence and the deliberate formation of a fistula as a method of correction or overcoming an obstruction can

prove most frustrating and disappointing It would appear that tissues exposed to contact with cerebrospinal fluid react in such a manner as to discourage the continued escape of fluid Certainly post-operative fistulas would be of more frequent occurrence in the absence of this reaction Anyway such is the tissue response that in order to guarantee the persistence of a fistula it is advisable whenever possible to introduce some agent as a barrier to occlusion

What might be considered an easy and positive way of forming a fistulous communication between the ventricular system and the subarachnoid space where a block develops caudal to the anterior end of the third ventricle (as, for example, by the development of a pineal tumour) would be by perforating the lamina terminalis A perforation at this site brings into communication the anterior end of the third ventricle and the cisterna chiasmatis However the permanence of such a passage cannot be guaranteed, for the margins are apt to adhere to adjacent arachnoid thereby sealing the opening. The close proximity of the optic chiasma hardly permits the retention of some foreign material as a hindrance to this occurrence.

Attempts have been made to overcome adhesion of the margins of an opening into the ventricular system One idea was to form a fistula at some other site such as through the corpus callosum or the parietal cortex, where sealing off is less likely to take place Supposedly the continued escape of fluid would keep the margins of the fistula apart and the concomitant tendency for the cortex to shrink away as the hydrocephalic ventricle diminishes in size would lessen the risk of adhesions. Walter Dandy recommended an incision into the side of the dilated third ventricle exposure being attained through the middle fossa by retraction of the temporal lobe However no really satisfactory means of guaranteeing permanency of any fistula has resulted.

The disappointing outcome of many cases resulted in the use of tubes of rubber or plastic not so liable to sealing off Torkildsen of Oslo introduced the operation of cisterno-ventriculostomy whereby a communication is made between the lateral ventricle and the cisterna magna One end of a rubber or plastic (polythene) tube is introduced into the lateral ventricle through a perforation of the skull in the posterior parietal region the tube is placed either under the scalp or extradurally and tracks down to the posterior fossa, where the other end is fixed into the cisterna magna One or two tubes will be needed according to whether or not free communication exists between the lateral ventricles Thus for a tumour obstructing the foramina of Monro (for example a suprasellar tumour) the extent of the operation would depend on the presence or otherwise of perforation of the septum lucidum In order to deal with obstruction at the posterior end of the third ventricle as from a pineal tumour or stenosis of the aqueduct drainage via one lateral ventricle only is required

Congenital hydrocephalus

An obstructive type of hydrocephalus is dealt with along the lines already discussed, except in those cases wherein there occurs an Arnold-Chiari malformation of the medulla and the cervical cord

External or communicating hydrocephalus

In hydrocephalus of the external or communicating type an imbalance exists

between cerebrospinal fluid secretion and absorption giving rise to progressive enlargement of the head

In order that control may be established either the secretion of fluid must be reduced or some permanent means of drainage instituted To diminish the secretion of fluid the choroid plexus must be destroyed or removed For the purpose of drainage some form of fistula must be made to connect the subarachnoid space to some channel of escape.

There are various means of connecting the subarachnoid space to certain body cavities, to vascular or to other channels. Direct drainage has been tried through a perforation of the tegmen tympani whereby drainage into the middle ear has been brought about Plastic tubes have been inserted between the subarachnoid space and the external jugular vein with or without a wick of silk or plaited plastic in the lumen of the tube. The renal pelvis has been joined to an opening in the spinal meninges in order to introduce drainage via the ureter A tube has been introduced running between the spinal subarachnoid space and the peritoneum and even a perforated tantalum screw has been inserted with the head of the screw in the spinal subarachnoid space and the screw itself in the body of a vertebra with the intention of permitting the escape of the fluid into the diploe from where absorption occurs.

DRAINAGE OF CYSTS AND OTHER ACCUMULATIONS OF FLUID

Accumulations of fluid are not unusual features in either the brain or the spinal cord and they arise from a number of different pathological states Two such pathological conditions are cystic cavities of gliomatous origin and cavitation of the spinal cord in the form of syringomyelia

Gliomatous cysts may contain tumour masses, mural nodules, or actually represent the cavity of a degenerating tumour of which the wall is the growth and the cystic content liquefied tumour tissue, or exudate. A collection of fluid may be dealt with by aspiration but it is often necessary to ensure that there is no re accumulation One means of preventing this is to create permanent drainage of the cystic cavity by opening it freely into the lateral ventricle or even sometimes into the fourth ventricle

Syringomyelia is not a disorder that responds to surgical intervention as a general rule. However expansion of the spinal cord can induce a state of spinal compression that calls for relief Again there may be the need to avoid further fluid collection In attempting to ensure ready communication of the cavity and the subarachnoid space it is sometimes possible to introduce tantalum foil as a precaution against reunion of the split cord tissue

PREVENTION OF EPILEPSY

Reference has been made already to the introduction of various materials for the purposes of separating the brain from other tissues, especially with regard to the formation of adhesions The comments however were related more to facilitation of surgical technique than to sequelae such as epileptiform states

Scar formation is to be expected but it must be reduced to a minimum. Any damage to the head resulting in laceration of the investing membranes of the brain is liable to produce epilepsy as a sequel Equally important is haematoma formation for the amount of residual scar will be proportional to the size of the haematoma Without doubt, the extent of cicatrization and gliosis plays a part in the incidence of epilepsy arising as a result of head injury

The area of raw surfaces of surgical origin must be reduced especially where adhesions may result. To this end it has been advocated that brain should not be allowed to remain in direct contact with bone and furthermore surgeons should apply some form of protection to cut surfaces of the brain as for example, follow ing lobectomy The object is to apply a non irritant protective surface as a *protection against adhesions*

Coatings of amnion and of cellophane or polythene film have been advocated for application to raw surfaces of brain, but there is no evidence of any advantage to be gained from their use What does seem to be important is the extent of adhesion of the brain to overlying structures, and steps taken to restrict this would appear to be of value. Certainly release of adherent scars does appear to reduce the incidence of epileptiform manifestations in some patients but on the whole release of adherent brain is more effective in relief of headache

OBLITERATION OF CRANIAL DEFECTS

Dura mater

Dural deficiencies are best restored by insertion of fascial grafts obtained from the temporal fascia or from the fascia lata of the thigh. Should the reconstruction involve restoration of more than one plane of tissue it is wiser to carry out the replacements in stages The cerebral part of the repair and insertion of a dural graft may be undertaken first. The restoration of the cranial vault is carried out later

Cranial vault

There is little doubt that any large deficiency in the cranial vault is better cor rected Just how large a defect must be to give rise to symptoms is uncertain for a good deal depends on the individual concerned From experience of a large number of cases with cranial defects the impression is gained that any defect larger than one inch in diameter can cause symptoms There is always the con viction that the nearer the patient's condition approaches normality the better for that patient

In a child there is not the same need for restoration as many defects become much smaller with the passing of time During school, as well as for games a plastic or leather prosthesis can be worn to avoid undue risk The author prefers to defer reconstruction until a child has developed fully

The situation of a deficiency also influences in some measure the need for treatment Where there is a good covering of muscle over the defect that protects the brain adequately reconstruction is not essential Nevertheless the awareness of a patient that damage has been sustained may cause him apprehension and embarrassment Still more apprehension arises when evidence of injury is apparent

to others. There are of course those unfortunate people whose obsessional natures may give undue concern where the defect is only slight. For instance there are persons who have been submitted to leucotomy who express uncertainty and displeasure at dimpling of the scalp over the sites of the skull perforations. Indeed some of these people demand that the defects be obliterated. For the purpose plastic buttons are obtainable as inserts into bony openings. The author has avoided any chance of concern on the part of his patients by performing the operation through a trephine opening and replacing the disc of bone before closure of the wound.

Autogenous bone

The author's experience of cranial defects, extending over a large number of cases arising out of two wars leads to the conclusion that final reconstruction is best effected by the use of autogenous bone. The choice of bone rests between the more spongy and mouldable bone of the iliac crest and the firmer contoured but more brittle bone derived from ribs. The majority of defects are suitable for iliac bone but larger defects are bridged more easily with ribs. Retention of the bone can be effected by various means, according to the individual preference of the surgeon. The author prefers to retain the bone in place by envelopment between the dura and reflected pericranium. It is thereby possible to retain it without screws or wire and to maintain good contour during healing.

Metallic and plastic plates

However for one reason or another some form of plate may be advisable, consisting either of tantalum or of plastic material. As far as the contour of a plate is concerned the result is satisfactory and aesthetic but there is a considerable risk that sooner or later a plate may be extruded or have to be removed. Should a plate lie subjacent to the border of a muscle insertion the continued action of the muscle can cause the plate to move even to fracture. One of the greatest risks is that at some time or another the patient will receive a blow in the region of the scar as a result of which the scar splits, thereby exposing the margin of the plate. In these circumstances the tissue response to the presence of a plate can be seen. Usually a smooth lining to a kind of sac is found or occasionally there may be an irregular surface of pale granulations subjacent to the plate.

During and subsequent to World War I Celluloid plates were commonly used. As a means of retention the prostheses were perforated. The fibrous reactions around the plate penetrated the holes and acted as an anchorage. Unfortunately the majority of these plates had to be removed. Owing to the degree of fixation removal of the plate proved most difficult and often necessitated excision. Infection was a more serious matter in those days but nowadays with antibiotics, infection no longer holds the same grave outlook.

Whatever benefits are described in favour of metallic or plastic plates they can never become part of the body structure, for actual fusion cannot take place. Yet other objections are to be raised against metal plates where any delayed complication arises. Anything that prevents satisfactory radiographic examination may cause serious difficulty should a cerebral abscess develop.

World War II saw the introduction of plastic plates of acrylic nature. There

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are still those who advocate the use of plastics in the restoration of defects, although the author feels obliged to produce guarantees of permanency of results. As he has had to remove many plastic plates from time to time confidence in their complete adoption must be discounted

All skull defects are not of traumatic origin Congenital structural abnormalities may sometimes also need obliteration

CHAPTER 10

PLASTIC SURGERY

T P KILNER AND J S CALNAN

SURGEONS WILL CONTINUE to bury foreign substances in the human body in their attempts to replace parts which have been lost or damaged by injury or disease and to construct parts which are ill-developed or have failed to develop All this is very laudable since it should save patients time and discomfort for there are many occasions when autograft homograft or even heterograft material is absent or is not available in sufficient quantity or in the desired condition

In spite of all the good results which have been obtained by such means it is the writers opinion that sooner or later the body attempts to reject such foreign material and it therefore can never be considered the ideal substance for the purpose. If this is borne in mind, then there are to be found many situations in plastic surgical work where foreign substances may provide pleasing and sometimes long lasting results. The whole question is so much alive that a special journal (*Transplantation Bulletin*) is now devoted to work in this field

At the beginning of this century beef bone chicken bone and ivory were often removed from patients on account of inflammatory reaction In those days plastic surgeons were imbued with the idea of replacement in kind—skin for skin bone for bone cartilage for cartilage—and also with the conviction that these materials should come if possible from the patient himself although cartilage with its absence of blood vessels was found to be suitable for homo-transplantation and occasional successful results were claimed from similar transplantation of bone The recent swing of the pendulum in favour of foreign substances is due to the discovery of synthetic or metallic materials which are biologically inert, producing little or no reaction in the tissues in which they are buried There can be little doubt that the relative immunity to infection given by antibiotics in the immediate post-operation period has played its part in this increased popularity The materials employed fall naturally into two groups—heterografts and foreign substances proper

HETEROGRAFTS

The heterografts which have been used are ivory animal bone bovine cartilage and ox fascia

Ivory and bone

Ivory was at one time very popular more particularly in continental clinics for building out the depressed nasal bridge line or the receding chin Many such implants were extruded as the result of infection within a few days of operation but some became encapsuled in firm fibrous tissue and exhibited immunity to infection and extrusion for many years. They sometimes shifted their position and so gave rise to somewhat grotesque deformities often worse than the original

conditions Beef bone implants followed a similar course sometimes being extruded soon after operation sometimes undergoing resorption but rarely persisting permanently The writers have never had an opportunity for testing the Swedish bone grafting material os purum which would seem to provide a sound scaffolding for bone growth.

Bovine cartilage

Put on the market in sterile condition bovine cartilage promised an enormous field of usefulness for restoration of contour in nose cheek and chin It seemed the ideal material for giving the desired stiffening to reconstructed ears in small children for whom autografting was impracticable or undesirable With a few notable exceptions these implants have undergone slow aseptic necrosis and have ultimately disappeared (Gillies and Kristensen 1951 North 1953 Gibson 1954 Gibson and Davies 1955) The few exceptions still under observation, make one wonder whether there may be a certain type or source of such cartilage which will supply more permanent results In the meantime, so long as it is realized that resorption will take place within two years, this material has a useful place in reconstructive surgery in childhood it can be replaced later by something of a more permanent nature.

Fascia lata

An adequate quantity of fascia lata can usually be obtained from the individual young or old, and has proved more suitable for slinging up the paralysed face than has preserved ox fascia which although it persists, has given rise in the writers experience to an alarming initial reaction

FOREIGN SUBSTANCES

Non-metallic

Nylon

Monofilament nylon running in a polythene tube has been suggested as replacement material for a lost flexor tendon in the hand (Sarkin 1956) Braided nylon has been used, as the general surgeon uses it, for hernia repair for darning the defect left in the abdominal wall after burying the bladder muscle in cases of ectopia vesicae. Terylene in sheet form has been recently used for the same purpose (Wostenholme Lotman and Malament, 1957)

Sponge polythene

In foam " form it has been used for breast contour and for reconstruction work in this region (Rubin 1951 Moore and Brown 1952 Rubin and Walden 1955) The writers have never employed it in this way and know of many disastrous results Even if accepted without infection such material changes in consistency and may become unnaturally hard ("marble breasts") for this region Polythene tube has been employed for stiffening of the helix margin in ear reconstruction (McCash 1957) Polythene as a solid block can be carved with a knife when warm and has been implanted in the nose chin and ear to define contour (Heanley 1954) Polythene tubes and moulds are also used as forms on which to apply free skin grafts in reconstruction of the pharynx and larynx after excision of these

organs for neoplasm (Negus 1953 Moore and Faulkner 1953) and in constructing a vagina in cases of congenital absence Polythene used in this way is extracorporeal and is removed once it has served its purpose

Acrylic

Acrylic is hard material and has been used to restore contour in cases where bone is required in defects of the skull malar cheek regions nose and chin (Dencer 1955) The acrylic is prepared as a moulded plate made to pattern on a plaster cast of the defect it is required to restore and when inserted subcutaneously requires fixation to the adjacent bone by stainless steel sutures or screws

Celluloid

In thin sheets, celluloid has occasionally been used as stiffening material to support a lower eyelid or a reconstructed ear margin

Metals

Stainless steel wire

For many years stainless steel wire has been used for suturing skin or buried to unite deep tissue and has been found satisfactory although it fractures after some years and may demand removal It is commonly used for the fixation of bone grafts to hold the bones in apposition in fractures of the mandible or fingers and has even been used to stiffen a reconstructed ear margin Its use for interdental wiring is well established Stainless steel wire of thicker calibre has been used between the ends of the cut mandible as a " bone spacer " in cases where resection of bone has been carried out and replacement in kind is not contemplated immediately It here serves the valuable function of holding the bony parts in their anatomically correct positions and so preventing secondary deformity

Tantalum

Tantalum wire has been used in a similar way in the fixation of bone grafts in the skull. As a perforated sheet, swaged to exact size and shape on a stone cast tantalum has been implanted to restore contour to the cheek nose and skull In a large number of cases the tantalum implant has shifted its position over the years and quietly perforated the skin or mucous membrane in other cases recurrent attacks of aseptic inflammation at long intervals have been noted. It has thus come about that nearly all tantalum implants have had to be removed.

Vitallium

More recently Vitallium has been introduced and is used in much the same way as tantalum A modern use is as an orbital implant around which the cone of ocular muscles can be sutured and into which an artificial eye may be inserted to give a " moving " prosthesis (Karakashian 1957)

EXTRA-CORPOREAL PROSTHESES

Many of these foreign substances plastic and metallic have been employed in the construction of external (extracorporeal) prostheses to camouflage facial disfigurement as a temporary or permanent measure where reconstruction in " flesh and blood has been delayed or has proved undesirable.

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CHAPTER 11

TENDON REPAIRS

RONALD FURLONG

INTRODUCTION

GOOD FUNCTION after division or rupture of a tendon depends on successful coaptation of the ends followed after healing by adequate gliding of the tendon as a whole Treatment is a dual problem and usually it is the second component which causes the surgeon more trouble Certain controlling factors have to be considered

It is not possible, purely by tension to rupture a normal tendon The inference to be drawn from this fact is that if a tendon does rupture it must have been abnormal at the time the force was applied to rupture it. This is a clinical experience and it has been proved experimentally It is also known that the abnormality is a degenerative process probably of vascular derivation It is reasonable to suppose that the prognosis following repair of a degenerate tendon is not as good as that following suture of a freshly cut normal tendon.

Furthermore the bed in which the tendon lies at the point of division can have a profound effect on the prognosis of repair A tendon in order to unite has to call on the surrounding tissue for a blood supply The adhesions through which these new blood vessels pass are likely to be more dense if they are derived from a fibrous tendon sheath than if they arise from loose long fibred areolar tissue. These and other factors have been responsible for all sorts of variations in surgical technique aimed at securing tendon union unaccompanied by permanent adherence Since surgery has ceased to be complicated by suppuration many different concepts embodying the use of foreign materials have been applied to this dual problem

THE PROBLEM OF TENDON COAPTATION

Tendon Rupture

Examples of tendon rupture comprise a special problem that is considered separately

Tendo achillis

If a ruptured tendo achillis is exposed immediately after the injury it is found that both ends of the tendon are profoundly degenerate This change extends for at least an inch on either side of the separation The opportunity for observing this is not very frequent because the early diagnosis of a ruptured tendo achillis is not as easy as might be supposed The degenerate tissue which is friable fragmented and bloodstained, accepts sutures badly so that sometimes local end to-end apposition is not attempted It was Bunnell who suggested that coaptation of the tendon ends could be achieved by short-circuiting the normal insertion of the

calf muscles into the os calcis using a stainless steel wire of appropriate strength. The short-circuit is achieved by passing the wire transversely across the junction of the calf muscles into the conjoined tendon the wires then pass distally parallel to the tendon and on each side of it as far as the os calcis Here the wire may be tied together over a suitable pad to protect the skin and in sufficient tension to approximate the ruptured surfaces of the tendo achillis This is a kind of suture " at a distance " which is more effective in holding accurate coaptation than local sutures through the degenerate tendon could ever be In order to protect the wire from undue strain the foot is held in plantar flexion by an external plaster splint which supplements the spurious temporary insertion of the calf group into the os calcis by stainless steel wire

Other examples of tendon rupture

The notable examples of rupture in this group are the tendons of the supraspinatus and the extensor pollicis longus muscles In the past attempts have been made to suture the ruptured supraspinatus tendon but these have been largely given up because of disappointment. The stitches do not hold and an unsatisfying suture is obtained The short-circuiting or suture at a distance " principle has been tried. To use a wire temporarily as an insertion for this muscle is attractive in theory but difficult to apply in practice The final discouragement was the fact that the outcome of rupture of the supraspinatus tendon, in all but massive or complete tears was equally good whether or not the patient was operated on

Attempts have been made to restore continuity of the extensor pollicis longus tendon by direct end to-end suture It is quite possible to make the stitches hold in the degenerate tendon ends but the rupture always takes place within a fibrous sheath at Lister's tubercle Adherence between the degenerate tendon ends and the fibrous sheath always proves too resistant to permit subsequent function Restoration of function following this episode is normally achieved by a tendon transposition which employs a totally different concept.

Tendon division

Without loss of tendon substance

In this example of tendon division and with no loss of substance, suture presents no great difficulty provided that interval between division and suture is less than 8 weeks The suture material needs to be strong enough to withstand tension due to normal muscle tone Much of the distracting force can be neutralized by appropriate joint posture Until recently there was controversy as to the best suture material for the purpose

Absorbable sutures that is to say catgut, are no longer used on account of the scarring that inevitably follows the inflammatory reaction of absorption. Silk, linen thread, or stainless steel are the present day favourites. Each of them has its devotees and there is not a great deal to choose between them Stainless steel is, however considered by many to be the best all-purpose suture. It is thin in comparison with its strength and it is easy to prepare and use Clinical observation reveals that no inflammatory reaction is provoked by stainless steel Re-exploration of a suture line reveals steel sutures lying dormant in physiological tissue There seems no point in using silk or thread neither of which has any advantage over steel wire

Bunnell (1956) developed a technique of suture in which the material can be with drawn when tendon healing is complete The method was used to implement the aphorism that the suture provoking the least reaction is the suture that is absent Before stainless steel wire was available for surgery Bunnell used silk and he developed the withdrawable technique to enable him to remove it at a pre determined time thereby limiting to the minimum the reaction of the tissue Since stainless steel wire has come into more general use the method has been largely abandoned and is now only used on occasions where there is considerable tension such as is likely to be met with when suture has been much delayed The with drawable wire does not now fulfil its original purpose of reducing adherence it is used as a tension wire to relieve a suture line from too much distraction

McKee in 1945 reported a novel method of tendon suture that was a by product of a method he was using to prevent adhesions from forming at a conventional suture line The device consists of a split tube of stainless steel the diameter of the tendon and about 1¼ inches long It is furnished with barbs sticking out of its internal aspect. The tendon ends are mobilized and brought into apposition and the tube is clipped into place about them The barbs plunge into the tendon and prevent the ends from pulling apart After an interval of 5 weeks the tube is removed The method ensures correct end to-end apposition without unsatisfied surfaces remaining. The disadvantage however of a second exposure is obvious and the method does not commend itself to general use If the contraption lies in the finger the joints are held in a constrained attitude that helps to produce stiffening. Furthermore, it is wrong in conception The surrounding tissue should participate in the union of the tendon ends, they themselves being relatively avascular This device sequesters the suture line and union is slow In practice it is found that the tendon ends are apt to pull apart even at 6 weeks following removal of the anastomotic tube This fact reduces the enthusiasm and purpose of early active treatment

In normal circumstances the conventional methods of suture are almost always used Similarly stainless steel wire is the suture material of choice There are two varieties The single strand of stainless steel wire of gauge 36 38 or 40 is extremely useful but the wire must be soft and malleable and not springy The alternative suture to this is even more malleable It consists of three fine strands of wire, twisted together Because of its make-up the wire is almost impossible to kink. A kink is fatal in a single-strand wire since a fracture at this point is in evitable even with the most trivial tension. On examining a suture line some months or years after the suture has been performed it is often found that the single strand wire has become fragmented. This is probably of no disadvantage but it does not happen if the twisted three strand wire has been used All in all therefore it is probable that the twisted wire is superior to the single-strand wire not only in its behaviour within the body but also in its adaptability and ease of use

With loss of tendon substance

If the injury has resulted in a loss of tendon substance causing deficiency between the ends that cannot be made good by apposition some method must be found to bridge the gap Such a gap is most often produced because a portion of tendon has to be sacrificed after it has been damaged beyond reasonable hope of functional recovery This state of affairs in the tendon can be produced either by its adherence

for some distance to a surrounding tendon sheath or the tendon itself may become degenerate and friable if it has been divided and not subsequently gained a secondary attachment. In such a case the tendon being without any tension for some weeks undergoes fibrous degeneration and finally becomes useless for repair

Free tendon grafting, comparable with full thickness skin grafting, is the obvious method of choice to make up such a deficiency It is freely used today especially in the hand and the technique has been brought to a fine art and the results generally are good Before the days of free tendon grafting, however much time and thought was spent by surgeons in attempting to devise a method to restore tendon continuity by the use of foreign material as a scaffolding, along which tendon tissue could grow from either end thereby making up the deficiency In 1914 Henze and Mayer used a silk scaffolding to bridge a deficiency in a tendon They reported that a fibrous substance that was not histologically tendon tissue ramified amongst and along the silk scaffolding, but that local adherence to the surrounding tissue was dense and firm This adherence could not be abolished though some movement did occasionally take place if the silk strands had been embedded in subcutaneous fat or had been lying in a undamaged synovial tendon sheath, as for example in the case of the tendo achillis In 1939 Wheeldon bridged a five inch gap in the extensor pollicis longus tendon with four strands of heavy black silk This he surrounded with a cellophane sheath to prevent adherence. He reported good movement afterwards This work was repeated by Trevor and reported in 1950 He used nylon instead of silk and dispensed with the artificial sheath In half the number of patients that he first reported he had, at a later time to remove the suture because of sepsis, but he claims that he found a tendon like material bridging the gap This method however is not in general use to restore function following spontaneous rupture of the extensor pollicis longus tendon at Lister's tubercle Tantalum wire has been used to bridge a gap in tendon in a similar way by Arkin and Siffert (1953) but they reported disappointing results because of an adherence between the so-called new tendon and the adjacent tissue

Summarizing these efforts it would seem that the results obtained by substitution of a tendon by a foreign material are capricious and not encouraging On the other hand the results of free tendon grafting are generally superior and are obtained by a technique of less complexity The methods of foreign body substitution which in their day were ambitious and advanced have been entirely replaced by the free tendon graft which being autogenous, is obviously likely to lead to a more successful result than could be obtained by the use of any foreign material

THE PROBLEM OF TENDON GLIDING

This represents the main obstacle to a good result after tendon repair Adherence of the suture line to the surrounding tissue is apt to occur even when there has been no loss of tendon substance and when the technique of suture has proved to be agreeably easy Suture of the tendo achillis leads almost always to a good result because the tendon follows a straight course and lies in a synovial sheath which is not encased in a fibrous tunnel Similarly suture of the extensor tendons on the back of the hand is likely to be successful because the tendons in this region are

surrounded by long fibred areolar tissue which in itself is capable of a good deal of movement. In the case of the flexor tendons of the fingers the situation is quite different: here the tendons are lying closely enclosed in a fibrous tunnel, adherence to which is notoriously constant.

The difficulty of obtaining and maintaining tendon movement falls into two parts. First, how to prevent adherence in a normal or undamaged sheath and secondly, how to make a new sheath should this be necessary. A definition is called for. A tendon which follows a straight course without deflection is usually surrounded by paratendon, that is to say, loose long fibred areolar tissue. Movement of the tendon is absorbed by the elasticity of the tissue, there being no single plane of gliding movement. The exception to this is the tendo achillis which although it follows a straight course is not surrounded by paratendon. It lies, in fact, within a synovial sheath or tube, there being a definite plane of gliding between the tendinous synovial layer and the parietal synovial layer. This arrangement is necessary because of the great excursion of the tendon.

Where tendons pass over joints they normally follow a curved course because deflection is necessary to accommodate joint movement. Here they lie in a synovial sheath between the layers of which the actual gliding takes place. Outside the parietal layer, however, there is always a fibrous tube which controls the position of the tendon, thereby maintaining its correct course. In the case of the fingers where the flexor tendons have to reverse their direction of pull by 180 degrees, the fibrous tissue sheath is all-important to hold the tendon in close apposition to the phalanges. If a suture line by reason of the site of tendon injury comes to lie within a fibrous sheath, adherence is very likely to occur in spite of the fact that the damage to the parietal synovial layer is minimal. Where, therefore, a tendon is divided within a fibrous sheath, it is usual to take special precautions by dividing the sheath at the point of suture and leaving it wide open. This procedure allows for swelling at the suture line and has been found to diminish the density and the degree of adhesions which follow. Suture is not ordinarily performed in the fibrous digital sheath because of almost invariable adherence. Continuity of tendon is usually restored by means of a tendon graft whereby the suture line can be transferred from the finger into the palm, where adherence is less likely. Generally the results of tendon suture in a synovial sheath are good because the adherence necessary to assist the union of the tendon ends is lighter in texture and capable of more excursion than the adherence which forms physiologically when a tendon suture lies within a fibrous sheath.

Use of material to replace damaged surroundings

When the surroundings of the tendon, including the synovial layer, are much damaged, the chance of adherence of the tendons is considerably greater. Surgeons have attempted for a generation or more to prepare a new gliding mechanism to replace the normal anatomy that has been destroyed by infection or injury. Gonzalez, who reported his experimental work in 1949, has done a great deal of work on the subject by trying to introduce, successfully, a smooth sheath of foreign material. He found that gelatine sheet was quite useless on account of the intense foreign body reaction induced. He next used cellulose acetate-phthalate, which is a substance sometimes used for coating enteric capsules. This material is broken down in the body and leaves formidable scarring. Absorbable plastics proving

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to be unusable Gonzalez turned to polythene This as far as the tissues are concerned is an innocuous plastic with encouraging experimental properties. Gonzalez, in the experimental animal divided a normal tendon and then repaired it by a conventional suture line This he surrounded by a polythene tube, thereby sequestering it from the surrounding tissue This is an unphysiological procedure which is bound to retard healing of the suture line. It was found that no tendon was healed before 29 days, and on an average it was necessary to protect the suture line from force for 40 days or longer to prevent separation during normal activity Similar results relating to the slowed rate of tendon healing had previously been reported by McKee as a result of his experience with metal anastomotic tubes. Up to date, no results of a sufficient number of operations have been published from which to draw conclusions as to the late results The method could be put to valuable use The encasement of a tendon freed from adhesions by tenolysis is an obvious corollary to surrounding a suture line to prevent postoperative adhesions The idea is good but the polythene tube has to be split to get it round the tendon after tenolysis and granulation tissue is apt to wander through this split, permitting adhesions to form These are divided when the polythene tube is removed one month later and it is reported that they do little to hinder movement.

In 1937 Lloyd Davis and Aries published the results of animal experiments they had made with the same idea of preventing adhesions after nerve and tendon suture They used various materials, but in their hands the material which consistently gave reasonable results was allantoin It was found that the excursion of the tendon was quite good during the second month after insertion but at a later date the range of movement was apt to become slightly restricted, presumably due to adhesion formation The loss of movement was not serious.

Use of tissues to repair damaged surroundings

The difficulties and disappointments attendant on the insertion of artificial material either as a barrier against adhesions during suture healing or as a permanent smooth-lined tunnel led to investigation along another line Mayer and Ransohoff had the idea that perhaps the tissues themselves could be induced to form a smooth lining to a tunnel artificially constructed

In 1936 they described the method whereby they used rods of celloidin laid into the tissue along the course of a previously destroyed tendon The old scarring was removed and the celloidin was sutured to the stump of the profundus tendon in the finger At some time between 4 and 6 weeks the second stage was performed in which the celloidin rod was removed and a flexor sublimis tendon with its synovial layer was passed through the tunnel and sutured at either end in the conventional way Good results were reported, particularly regarding the minor nature of the adherence of the graft against the constructed tunnel This method of constructing a tunnel and allowing the patient to furnish it with a smooth lining to which a tendon will not become adherent is in use today Silicone is used instead of celloidin but the technique used is almost the same as that described twenty two years ago by Mayer and Ransohoff

In 1935 Thatcher was experimenting with the use of steel rods lying in the course of the digital sheath. The purpose was the same namely to fashion an endothelial-lined tunnel into which a tendon could be placed with some prospect

of function Clearly the disadvantage of a rigid steel rod could be great in that stiffness of the interphalangeal and metacarpo-phalangeal joints would almost certainly result from immobilization for the six weeks that is necessary for an endothelial lining to form

This disadvantage is overcome by using a flexible and inert rod as a space occupant, along and around which an endothelial lining can grow The popular contemporary material is silicone which can fulfil both requirements A rod ¼ inch in diameter is used At the time of insertion the remains of the doomed tendon are removed and the silicone rod is laid along the phalanges so that it extends from the distal phalanx to the middle of the palm When the wound is soundly healed passive flexion of the finger is encouraged At the end of twelve weeks the silicone rod is removed through an appropriate incision in the palm A free tendon graft is threaded through the endothelial lined space attached to the terminal phalanx and sutured to the motor tendon in the palm The prospect of gliding and function is good

At the present time it is possible to construct a smooth endothelial lined tunnel into which subsequently a tendon can be placed This, unfortunately is not the tremendous step forward that it would seem to be because by using a tendon inhabiting paratendon preferably the palmaris longus, as a free graft, it is un necessary to create a smooth lined tunnel since a tendon graft of this nature carries its own gliding mechanism with it and so can be transferred anywhere There are however examples and circumstances in which it is advantageous to create a smooth lined tunnel within the finger as a preliminary to tendon repair

SUMMARY

The use of extraneous surgical materials in a repair of tendon can be summarized as follows As a suture material stainless steel is now the favourite largely because it is totally inert and its strength to diameter ratio is high Furthermore it is easy to use and is readily available. Of the two types of suture available the twisted three-strand variety is the better

There is now no cause or occasion to attempt to span a gap in a tendon by some foreign material This gap is now adequately closed by an autogenous free tendon graft using a standardized technique.

Foreign material when implanted particularly in a finger or at the wrist, can be used to persuade the body to line the tunnel so formed with a smooth endothelial layer comparable in its slipperiness with synovial membrane. This technique has now been modernized and is here to stay It has certain advantages on occasions Probably with greater experience in the use of inert plastics, the method can be developed and will have applications in other sites to correct other disabilities

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CHAPTER 12

THORACIC SURGERY

T HOLMES SELLORS

APART FROM THE USE of synthetic fabrics in cardiovascular surgery there is not a great need for foreign material in thoracic work Most of the operations on the lung are concerned with excision and reparative operations on such structures as the bronchus and trachea are not often demanded On the other hand the use of plastic and non-absorbable ligatures and sutures is widespread There is no particular objection to the use of catgut but linen silk and plastic thread have the advantage of greater tensile strength and easy handling of the long lengths that are required within the depths of the thorax. Black ligature or suture material has the merit of being more readily seen inside the chest than a white one stained with blood The ligation of great vessels such as the main pulmonary artery or pulmonary veins can be carried out by one or more stout single threads and a useful method is to use a double strand Ballance knot to close these channels It is essential that the divided cuff of the vessel that has been tied should be large enough to prevent it from slipping through the ligature.

BRONCHUS

The suture of a bronchus that has been divided requires a considerable amount of care Until recent years there was a high incidence of bronchial fistula following lung excision and when this occurs the broncho-pleural communication leads to infection of the pleural cavity It is important when dividing a bronchus in the course of lobectomy or pneumonectomy to ensure that no stump which might act as a potential pocket of infection is left behind. There is considerable variety in the methods of bronchus closure and in the choice of suture material A series of fine interrupted or mattress stitches of linen or silk is satisfactory and stainless steel is also used. Once an airtight closure has been achieved the stump is covered by adjacent tissue which helps to reduce the risk of a leak if the stitches cut out. A minor complication of bronchial suture sometimes arises from the foreign material ulcerating into the bronchus and causing an irritating cough which persists until the suture is removed through a bronchoscope or is coughed up

Plastic work on the bronchial tree is virtually confined to resection of short lengths of a bronchus with restoration of continuity by end-to-end suture Owing to the rigidity of the bronchi an everting suture cannot be used and the junction has to be carried out carefully with interrupted non-absorbable sutures which do not narrow the lumen.

TRACHEA

Excision of trachea is sometimes required if a tumour is present. Carcinoma of the trachea is rare but so-called adenoma is comparatively common After

removal of the tumour the deficiency has to be closed in such a way that the lumen of the tube is not obstructed and this precludes the use of any soft or loose patch or graft Consequently some form of framework has to be used as a preliminary A winding or spiral of stainless steel makes a satisfactory bridge in cases where the full circumference of the trachea has not been excised Over this steel frame a graft of skin or fascia lata is stitched and suction drainage of the pleural cavity is used so as to ensure early and complete expansion of the lung, which then adheres to the trachea and graft and prevents air leak

Excision of the full circumference of the trachea that leaves an appreciable gap between the two ends constitutes a problem that has not been fully solved. The movement of the trachea between the cricoid cartilage and the lung root is considerable and any prosthesis must be capable of lengthening and shortening without reduction of lumen A simple spiral covered by a loose graft might appear to be a satisfactory solution but the loose tissue frequently falls into the spaces between the spirals and partly obstructs the lumen We have attempted to use geodesically wound spirals of stainless steel with the free ends of the wire spot welded on to a small ring which is sutured to the cut ends of the trachea The framework is then covered by skin or fascia lata graft.

In the course of any tracheal reconstruction there are a number of anaesthetic problems to be considered and the endotracheal tube conveying the anaesthetic gasses will have to be inserted through the chest into the lower divided end of the trachea until the prosthesis is in place

DEAD SPACES IN THE CHEST

The bony cage of the thorax provides a rigid framework which cannot normally collapse or shrink on to any dead space that is produced by excisional surgery

Pneumonectomy

The problem of the dead space is best illustrated in pneumonectomy The hemithorax is left as an empty space which in the course of six months to a year fills in with fluid and fibrin aided by displacement of the mediastinum and elevation of the diaphragm and some flattening of the chest wall If it were necessary to close this dead space without producing mediastinal displacement an extensive thoracoplasty could be performed but this would lead to some external deformity It has been suggested that to maintain a central mediastinum a prosthesis should be inserted into the dead space. This can take the form of a polythene sponge shaped roughly into the form of the chest cavity Theoretically this type of procedure has many advantages but in practice in Great Britain the ordinary natural method of healing has not been found to give rise to significant trouble

Pneumolysis for pulmonary tuberculosis

In the operation of pneumolysis for pulmonary tuberculosis the lung is stripped from the inside of the chest wall and depressed to a level that provides adequate collapse In many instances the dead space is probably closed by rib resection in the form of thoracoplasty but where it is felt necessary to retain the ribs the space produced by the pneumolysis has to be maintained by refills of air at a high pressure or by the insertion of some form of filling material Twenty or thirty

years ago paraffin wax was considered to be a satisfactory medium It was soft and moulded itself to the shape of the space and so long as it did not become infected or extruded it maintained the lung in its collapsed position More recently plastic materials have been used These take the form of hollow spheres or solid balls which are loosely packed into the space Polythene sponge has also been used This operation of plombage has the great attraction of not needing an extensive removal of rib, but the risks are those of infection not so much by pyogenic organisms as by tuberculous infection of the dead space There is also a danger of pressure ulceration if the lung has any tendency to re-expand Plombage " operations have been fashionable from time to time but at present the trend towards excision has reduced the need for this form of surgery

DEFICIENCIES IN THE CHEST WALL

Deficiencies in the chest wall may result from injury or more usually from the wide excision of a tumour of the chest wall In the majority of cases division of ribs beyond the area of excision has enabled the surgeon to strut or bridge most of the gap which can then be satisfactorily covered by muscle and skin flaps There are however occasions when a gap in the chest wall is left and if it is not supported considerable herniation of the lung will result. This is most likely to occur in the region of the sternum and anterior ribs and if it is certain that the tumour has been adequately excised support may be given to the deficiency by the suture of tantalum or wire mesh across the exposed ribs This provides some form of support, but for mechanical reasons there may still be a certain amount of give or weakness, and in such cases it is probably wiser to consider the use of an acrylic or polythene plate which has been previously moulded to the shape of the chest This plate can be cut to the right size at the time of operation and can be drilled to take supporting and fixing sutures The plate is then covered by muscle and skin and on the occasions on which it has been used it has remained secure for a number of years There is quite a considerable field for this type of prosthesis in cases of breast cancer where the ribs are involved either by direct spread or as the result of post-operative radiation A wide clearance of necrotic rib and the preparation of flaps that have not been subjected to radiation may save the patient a great deal of disability and pain

OESOPHAGUS

In cases of obstruction of the oesophagus which usually result from carcinoma the ideal is to excise the tumour and to restore continuity by anastomosing the stomach or small gut to the divided oesophagus. Even if the tumour cannot be excised a palliative anastomosis allows the patient to swallow in comfort and prevents the discomfort and misery of a gastrostomy which is the only alternative to starvation The severity of major surgery on the oesophagus is such that in a debilitated patient the operative risk is high and there are cases in which mobiliza tion of the stomach or small bowel by resection is more than the patient can be expected to stand In these cases the alternative possibility is to resect the tumour locally if possible and to bridge the gap with a polythene tube as was advocated

by Burman If the tube can be held in place between the two ends of the oesophagus the patient will be able to swallow in comfort. The danger of this form of operation lies in leakage at the junction points and this occurs fairly commonly in spite of every precaution that can be taken Once a leak has occurred it is almost impossible to repair it in view of the poor state of the patient Infection of the pleural cavity is inevitable and the patient usually dies in a short space of time In spite of these risks the operation has proved of benefit in some cases.

CHAPTER 13

VASCULAR SURGERY

CHARLES ROB

THE REPLACEMENT of a portion of a blood vessel by either another blood vessel or a prosthesis of foreign material has been practised both experimentally and clinically since the early years of this century but many of the methods proved to be either ineffective or the success rate was so small that they were abandoned soon after their introduction Amongst these may be included glass tubes (Abbé, 1894 Tuffier 1915) extravascular tubes of ivory (Nitze 1897) or magnesium (Payr 1900) tubes of aluminium or gold (Carrel 1912) Vitallium tubes either with or without a covering vein graft (Blakemore Lord and Stefko 1942) and absorbable prostheses of fibrin (Svenson and Gross 1947) The only materials which have survived in clinical use until today are blood vessel grafts and transplants first used successfully by Hopfner (1903) in experimental animals and by Lexer (1913) in patients, rigid plastic tubes (Hufnagel 1947) and prostheses of pliable plastic materials (Voorhees Jaretski and Blakemore, 1952) The subject of the reconstruction of human blood vessels has recently been reviewed by Rob Eastcott and Owen (1956) and the scope and indications for this type of surgery discussed

BLOOD VESSEL GRAFTS AND TRANSPLANTS

In 1912 Carrel was awarded the Nobel prize in medicine for his work on the preservation and transplantation of blood vessels and organs and today he is considered to be the father of this branch of vascular surgery Blood vessels may be repaired by grafts or transplants of autogenous homologous or heterologous material Autogenous grafts are best because they survive transplantation and form a permanent living union with the host. Ideally an artery should be used to replace an artery and a vein a vein but man has no spare large arteries and so veins have to be used to replace arteries These work well for vessels such as the femoral artery which are supported by the tissues of the host but frequently rupture if used for the replacement of arteries within the body cavities. Homologous arterial transplants have been used widely in clinical practice either fresh or preserved in a variety of ways of which the best appears to be freeze-drying but they do not survive and merely act as a framework which is slowly replaced by the tissues of the host. Heterologous arterial transplants have not proved to be satisfactory and they are no longer used

PLASTIC PROSTHESES

Because homologous arterial transplants, either fresh or preserved do not survive but merely act as inert tubes any suitable material should serve as well Today

certain plastic prostheses give results when inserted into the aorta or its major branches which equal those achieved with homologous arterial transplants.

A plastic prosthesis may be either solid and rigid or porous and pliable. The solid and rigid prosthesis has the disadvantage that clots may form at the point of union between the tube and the host artery; these may lead either to complete occlusion or sometimes peripheral emboli. Today the only use for such a rigid prosthesis is to carry a valve as recommended by Hufnagel, Rabil and Reid (1954) for the treatment of aortic incompetence, but even in this situation clots may form and peripheral emboli result.

On the other hand, a variety of porous and pliable plastic materials have been used with very good early results. The first to use such a material were Voorhees, Jaretski and Blakemore (1952); they used vinyon N cloth (vinyl chloride-acrylonitrile) and by 1954 were able to report that they had used this material in 18 patients with satisfactory results. More recently a variety of other plastic cloths have been used, notably nylon (a superpolyamide), Orlon (an acrylic fibre), Terylene (a polyester produced also in the United States of America under the name of Dacron) and a multilayered cloth of nylon and polythene (Shumacker and King, 1954). Of these it appears that Terylene and Orlon are the best. The use of Orlon was pioneered by Hufnagel and in 1955 he published the results of his experimental and clinical work. He had inserted an Orlon prosthesis into 15 patients over a period of 16 months with good results. In Britain Kinmonth, Taylor and Lee (1955) have also found it satisfactory. Deterling and Bhonslay (1955) prefer Terylene (Dacron). A prosthesis of plastic cloth has been used on a number of occasions for the reconstruction of the aorta or iliac arteries in patients. One who had a large aortic aneurysm lying within a tuberculous cold abscess was reported in 1955 (Rob and Eastcott) and is of interest because a homologous arterial transplant would probably have ruptured because of the tuberculous infection whilst a plastic cloth prosthesis is working well 2½ years later. Fig. 60 shows a prosthesis of Orlon cloth in position in the thoracic aorta of a woman aged 26 years. It is bridging the gap which remained after a large aneurysm and an associated coarctation had been resected. This patient has had a normal pregnancy since her operation.

Polyvinyl-alcohol sponge tubes

The search for a plastic prosthesis suitable for the reconstruction of vessels of the size of the human femoral artery or smaller continues. The best materials to date appear to be polyvinyl-alcohol sponge, Teflon seamless cloth tubes, and a crimped silicone-coated chemically treated nylon tube (Edwards and Tapp, 1955). Polyvinyl alcohol sponge tubes prepared in the manner recommended by Shumway, Gliedman and Lewis (1955) and Owen (1956) gave good results when used experimentally. Over 50 per cent of polyvinyl alcohol sponge tubes inserted into the femoral artery of dogs were patent one year later. These good results led to the use of this material in patients and the initial results were encouraging, so much so that in 1956 it was reported ... Of the various plastic prostheses for use in the aorta we prefer poly vinyl alcohol sponge tubes to plastic cloths but of the cloths we have found Terylene and Orlon satisfactory ". Later experience has shown that many of these prostheses thrombose when used in patients and the use of this material has been abandoned, although it is interesting to speculate upon the reasons for its

FIG 60.—A prosthesis of Orlon cloth sutured into the thoracic aorta of a patient following the excision of an aneurysm and an associated proximal coarctation. The patient is well and symptom-free

success in the femoral artery of the dog and its failure in the larger femoral artery of man. A similar fate has followed the use of the crimped nylon tube and the seamless cloth tubes when used to replace a vessel of the size of the human femoral artery or smaller. The early results are good but the longer term results show that nearly all these prostheses have thrombosed by the end of 1 year.

Fig 61 illustrates one of the reasons why these prostheses thrombose when used to replace the vessels of a limb. This patient had a popliteal aneurysm with gangrenous toes. The aneurysm was resected and a plastic prosthesis inserted (Fig. 61*a*). The immediate result was excellent and the toes healed. Subsequent arteriograms with the knee straight (Fig. 61*b*) and in 90 degrees of flexion (Fig. 61*c*) showed a most interesting state of affairs. With the knee straight the arterial flow is apparently normal: in 90 degrees of flexion the prosthesis is straight and the host artery has been forced into irregular waves, so much so that some inches proximal to the prosthesis the appearances are as if a clamp has been placed across the artery. Probably this is due to a kink of about 300 degrees photographed head on. Some months later this prosthesis thrombosed, but by then the foot was healed and gangrene has not recurred.

Search for ideal plastic

The ideal plastic for vascular reconstruction has yet to be discovered, but several materials approach the ideal. First, it should be non wettable on the inside so that the blood will not clot, and wettable on the outside so that it may

FIG. 61.—(a) A crimped silicone-coated nylon tube in position after the excision of a popliteal aneurysm (b) a post-operative arteriogram showing the tube in position. Note the good flow with the limb straight (c) the knee of the patient shown in (a) and (b) has been flexed to 90 degrees. Note straight prosthesis and kinking of host artery One kink gives the appearance that a clamp has been applied across the artery a few inches proximal to the implant.

become incorporated in the tissues and not surrounded by a capsule It should be porous so that the host tissues can grow right into the whole implant and it should be biologically inert and not carcinogenic It should be flexible elastic and not liable to fragmentation or other physical changes as a result of the continued movements of arterial pulsation It should not leak excessively and should be easy to make into the required shape without irregularities and easy to suture into the blood vessels of the host Finally it should be cheap easily sterilized readily available and manufactured in such a way that the product has uniform characteristics

Perhaps the best plastic for the replacement of the aorta or its large branches such as the common iliac arteries is Terylene (Dacron) cloth with a taffeta weave the threads being 161 for the warp and 94 for the weft per inch the interspace size being as near 5 × 50 microns as possible and the air porosity of the material being about 4 cubic feet per square foot per minute

As stated there is as yet no plastic prosthesis which on a long-term follow up in man provides a patent implant for a vessel of the size of the femoral artery or smaller However there is a small place for such a prosthesis to replace such an artery when a vein graft is not possible and an arterial transplant is not available The flow will be restored for a variable period often 6 months, and the gradual thrombosis which then occurs will give time for the development of a satisfactory collateral circulation

The fate of a plastic prosthesis inserted into an arterial defect

Soon after insertion probably in less than 12 hours, the inner surface of the prosthesis becomes covered with a layer of fibrin or a fibrin like substance which over a period of days, weeks and months becomes invaded by cells which may closely resemble true endothelium The true endothelium however only grows out from the ends of the host vessels for a distance of about 2 centimetres This means that the lining of a prosthesis more than 4 centimetres long consists of true endothelium at each end and in the centre a layer of fibrin and cells resembling endothelium and probably derived from the blood stream Outside the prosthesis becomes surrounded by fibrous tissue which in the case of suitably permeable plastic materials grows into the prosthesis and incorporates it into the tissues of the patient

Technique of making a prosthesis of plastic cloth

The Terylene Orlon or nylon cloth is bought from a draper s shop and cut with pinking shears to the required shape It is then sewn with thread of similar material into a tube and sterilized by autoclaving before use A straight prosthesis as used in the thoracic aorta (Fig 60) is made by cutting a rectangle of the cloth of the appropriate size sewing it along one edge using a double seam (French seam) and then turning back the ends to form a cuff It should be made longer than is necessary and the length at the time of insertion can be varied by altering the length of the cuffs A fine needle should be used to make the seam and it can be sewn either by hand or on a slow sewing machine The prosthesis should be thoroughly washed with a detergent and then in water dried and sterilized by autoclaving. It is sewn into the patient with a continuous suture of fine silk or the appropriate plastic thread The actual suturing is more difficult with a

cloth prosthesis than either a homologous arterial transplant or a prosthesis of polyvinyl-alcohol sponge After removal of the clamps there is a certain amount of leakage greater with vinyon than with Orlon or Terylene This leakage can be reduced by treating the material with polyvinyl chloride but the simplest measure is to preclot the prosthesis by filling it with blood aspirated from the aorta It will then get soaked in blood or serum and the leakage greatly reduced Just prior to use any loose clots are washed out with saline

In the case of a bifurcation two λ-shaped segments of cloth are cut and sewn together as a pair of trousers with a seam on each side of each limb and of the stem The ends are then turned back as before

Seamless tubes have been woven and work well in clinical practice They are however not yet generally available

ARTERY BANKING

In general there are three methods of storing arteries—refrigeration (Carrel 1908 Gross, Bill and Peirce 1949) freezing (Eastcott and Hufnagel 1950) and freeze-drying (Marrangoni and Cecchini, 1951 Eastcott and his colleagues 1954) All have their uses refrigeration provides short term storage when facilities for the other methods are not available freezing provides permanent storage but the process is costly and transportation from hospital to hospital difficult freeze-drying provides storage at room temperatures and easy transportation The maintenance of an artery bank by the latter two methods will now be described

Selection of donor

The donor should have been under 35 years of age and not died of a transmittable disease Recent methods of sterilization have made it possible to utilize as donors those who have died from bacterial infections such as peritonitis The arteries are usually removed in an aseptic manner as for a surgical operation but if the grafts are to be sterilized an aseptic technique is not necessary The whole aorta both carotids and the ilio-femoro-popliteal arteries are removed Each branch is left about 1 centimetre long and the vessels are cleaned down to the adventitia They are then placed in a bottle of sterile isotonic saline and preserved in a refrigerator at a temperature of 4 C until banked They can be kept in this way for 4 or 5 days If the arteries have not been taken aseptically or there is any doubt about their sterility then they should be sterilized either by antibiotics (Fisher Wilde Adams and Fisher 1956) ethylene oxide (Hufnagel, Rabil and Reid 1953) *beta*-propriolactone (Szilagyi Overhulse and Lo Grippo 1954) or cathode irradiation (Meeker and Gross 1951) All work well and when it is available irradiation appears to be the best method

The bank

If the arteries are to be frozen they are placed in an empty sterile tube of Pyrex glass the tube closed with a sterile rubber seal and the tube and its contents frozen to 79 C by immersing the lower nine tenths in a mixture of solid carbon dioxide (dry ice) and alcohol after which the tubes are placed in a modified deep freeze—which runs at a temperature of − 20 C (Fig. 62) the special compartment

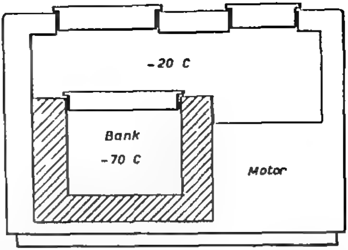


FIG. 62.—Diagram to show how a deep freeze has been modified to make a frozen artery bank

which contains the dry ice (Fig. 63) being kept at -79 C It is this need to replenish the dry ice which makes such an artery bank expensive and it is one of the reasons why freeze-drying is preferred

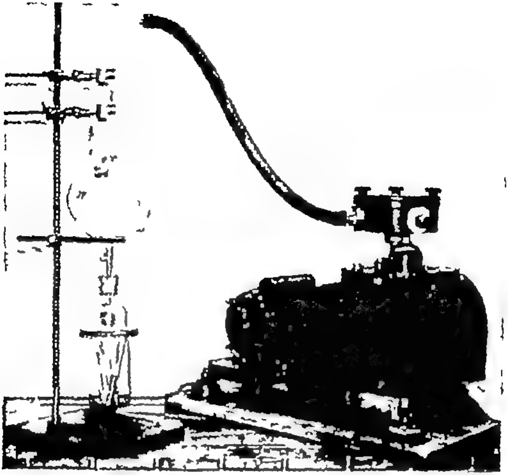
Process of freeze-drying

Freeze-drying or drying by sublimation consists of a very simple process and the necessary apparatus is not costly The grafts are placed in sterile glass tubes and frozen to -79 C They are then subjected to a high vacuum for a full

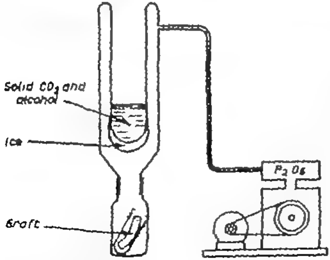
FIG. 63 —The interior of a frozen artery bank Note the blocks of dry ice.

working day; this removes about 97 per cent of the water and a further 2 per cent is removed by drying them under vacuum with phosphorus pentoxide after which the tubes are capped evacuated and sealed

Fig. 64 is a picture of a home made freeze-dryer A good commercial model is made by Edwards & Co Ltd As will be seen the grafts are first frozen and are then subjected to a high vacuum This removes the water from the artery by



(a)



(b)

FIG. 64.—(a) The freeze-dryer in use at St. Mary's Hospital, London, since 1953 (b) a diagram of the apparatus.

sublimation, a process which does not damage its structure. During the first part of the drying process the artery remains frozen because of the loss of latent heat during evaporation. As an extra precaution the container with the grafts

in it can be placed in a thermos jar containing alcohol and dry ice at − 79 C The water which leaves the artery is condensed as ice on the alcohol and solid carbon dioxide condenser just above it and any which passes this is trapped in the phosphorus pentoxide before the pump is reached

After secondary drying in an evacuated condenser over phosphorus pentoxide for 2 or 3 days, the tubes are capped evacuated and sealed with picien wax The arteries can now be kept at room temperatures for an indefinite period and transported as easily as any other glass tube.

Reconstitution

First the wax is removed from the tube then the rubber cap is cleaned with spirit The tube is now completely filled with sterile isotonic saline or distilled water and left for 20 minutes during this time the artery rehydrates and becomes ready for use. It is then removed from the tube, the branches are tied and it is ready to be inserted into the patient

THE TECHNIQUE OF ARTERIAL SUTURE

This takes a variety of forms but in general the end to-end and end to-side techniques are the most usual

After stripping the adventitia from the vessel on each side of the proposed suture line the surgeon inserts two stay sutures of No 0000 silk for the aorta and No 00000 silk for peripheral vessels. An atraumatic needle is best unless a plastic cloth prosthesis is being inserted, when it is wise to use an eyed needle because the atraumatic needle tends to bend and break as it goes through the cloth An over and-over suture is preferred because this suture does not narrow the anastomosis as an everting mattress suture does. When inserting an artery transplant considerable tension is required, otherwise redundant loops form when blood at arterial pressure is admitted into it.

THE PRESENT POSITION OF THE VALUE OF THE DIFFERENT ARTERIAL SUBSTITUTES

The accompanying Table gives the results obtained up to March 1957 at St Mary's Hospital with the various arterial reconstruction procedures and whilst these results depend to a great extent upon the reason for doing the operation they give a good general idea of the value of these procedures, particularly as many of the patients have been followed for as long as 7 years since their operation

264 ARTERIAL RECONSTRUCTION OPERATIONS

Operation	*Number of patients*	*Dead (including operation deaths)*	*Thrombosed early and late*	*Patent today*
Direct suture	26	3	1	22
Thromboendarterectomy	38	1	6	31
Autogenous vein	30	4	15	11
Homologous artery	116	12	35	69
Plastic cloth	27	6	0	21
Polyvinyl-alcohol sponge	27	6	12	8

The best results have followed the operation of thrombo-endarterectomy but this is really a matter of selection only the most favourable cases being treated by this operation Of the arterial substitutes homologous arterial transplants are the best, even though they have a higher failure rate than plastic cloth in this series The reason for the apparently better results with plastic cloth is that only this material has been used for the reconstruction of the aorta and iliac arteries where the mortality is higher but the thrombosis rate very much lower than with peripheral arteries, into which many homologous arterial transplants have been inserted As will be seen the good results with polyvinyl-alcohol sponge tubes in experimental animals have not been reproduced in man

To summarize

The best arterial substitute is a homologous artery When this is not available a prosthesis of plastic cloth is satisfactory for the reconstruction of the aorta and iliac arteries . Plastics have not worked well in the peripheral arteries here the best substitute when a homologous artery is not available is an autogenous vein graft.

OTHER USES FOR MATERIALS IN VASCULAR SURGERY

So far the replacement of segments of blood vessels has been discussed, but materials have been put to other uses in the management of patients with abnormalities of their blood vessels. Aneurysms have been treated by the introduction of steel wire into the sac (Blakemore 1947 Linton 1951) in order to encourage clotting and reduce the chances of rupture Fine stainless steel wire is introduced through a cannula or a needle and it fills up the sac leaving a channel in the centre surrounded by a mass of clot which has formed around the coils of wire As much as 700 feet has been introduced into a large aneurysm This method, although simple has not given really good results in clinical practice and today it is only used for a large aneurysm which for anatomical or other reasons cannot be excised

Another method reinforcing an aneurysm is to wrap it in polythene cellophane (Poppe 1949) This substance has the property of producing an intense fibrous tissue reaction when introduced into the tissues of the human body It is important to realize that the degree of reaction produced by cellophane depends upon the plasticizer which was used in its manufacture In the case of polythene cellophane this is dicetyl phosphate. As an alternative to wrapping an aortic aneurysm in polythene cellophane Berman and Hull (1952) have injected dicetyl phosphate mixed with olive oil around the aneurysm in order to produce the same result Again these methods, although attractive in theory have not proved satisfactory in practice and most surgeons with experience of this method have abandoned their use although good results have recently been reported after the enclosure of intracranial aneurysms in plastic

PLASTIC BLOOD TRANSFUSION EQUIPMENT

It is probable that all plastic equipment of the type designed by Carl Walter for the collection storage and infusion of whole blood will become standard equipment

in all countries with a blood transfusion service The equipment is made of polyvinyl chloride and other plastics and consists of a plastic bag in which the blood is stored a plastic drip chamber and plastic connecting tubes and adaptors It can be connected to a needle or a plastic cannula which is introduced into a blood vessel The advantages of such equipment include safety and freedom from reactions, easy storage and satisfactory performance in clinical practice Plastic cannulas and tubes have been used for many years for intravenous infusions when it is anticipated that they will have to run for several days

Lastly a variety of plastic valves and baffles have been used for the correction of cardiac valvular and septal defects. With the introduction of open heart surgery these are rapidly being superseded by direct surgical correction but they are still used in certain situations For example it is usually impossible to close an ostimium primium defect in the atrial septum by direct suture Under these circumstances closure may be achieved by the insertion of a patch of polyvinyl alcohol sponge

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CHAPTER 14

HEAD AND NECK

MAXWELL ELLIS

THE DEVELOPMENT of surgically inert plastic materials has led to a wider use of foreign material in and on the living tissues There is a call for external and visible prostheses to remedy deformity as well as for functional internal prostheses.

EXTERNAL PROSTHESES

Temporary prostheses

A temporary prosthesis can be worn while a facial defect is being repaired in stages, and may spare the patient a great deal of embarrassment and possibly psychological damage This situation occasionally arises after injuries, during the period of plastic reconstruction, and after a mutilating resection for cancer A temporary prosthesis can be fashioned from rubber latex, which is a soft and pliable material and can easily be tinted to a natural shade The flesh colour darkens gradually especially when exposed to the sun, but the lightness of the material and the ease with which it can be attached by glue or gum make it especially useful as a temporary fitting.

Permanent prostheses

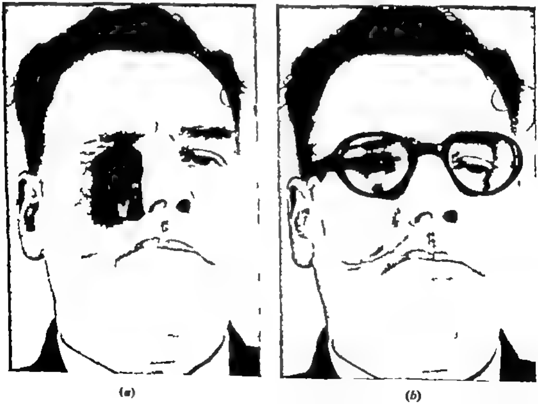
The value of permanent prostheses is to some extent a matter of opinion. The techniques of reparative surgery are extending, and many exponents of these skills would doubtless deny the need for a permanent facial prosthesis. Nevertheless the reconstruction of a whole ear or the complete nose is never a particularly successful procedure and the organ rarely looks at all natural. A prosthesis is a more aesthetically satisfying mode of repair and in spite of its disadvantages in having to be fixed in place, removed and cleaned, it is probably the more practical compromise The materials vary Vulcanite, with or without wax gelatine glycerin and a light aluminium alloy have all been used. A nose or an ear is best made of rubber latex (Fig. 65), and can be stuck to the skin firmly enough to take a pair of spectacles Other facial defects are best remedied by acrylic resin prostheses They are durable light, of good texture and easy to tint they do not corrode on contact with nasal or oral secretions and are easy to clean The type of defect for which an acrylic prosthesis is ideal is illustrated in Fig. 66 If this defect is later closed (by a lined tube pedicle graft from the forehead or chest), a flat expanse of skin will replace the gap, and can be concealed by a smaller but similar type of prosthesis.

Palatal defects

An opening in the hard palate is usually closed by the obturator of an ordinary denture The larger problem, after excision of the whole maxilla, is solved in the

(a) (b)

FIG. 65.—(a) Pinna with external table of bone excised and defect covered with skin graft (b) prosthesis of rubber latex secured by gum.



(a) (b)

FIG. 66.—(a) Defect following wide excision of maxilla and orbit (b) prosthesis of acrylic resin

FIG 67.—(a) Palatal defect after excision of maxilla (b) temporary prosthesis to repair defect of (a) (c) permanent prosthesis.

same way but in two stages. The immediate operative defect is sealed off with a previously prepared temporary denture the upper surface of which carries several wires protruding vertically for about 1 centimetre. The defect behind the cheek is filled with gutta percha moulded to the shape of the cavity fixed to the upper surface of the denture by impalement on the wires. This prosthesis is fitted at the end of the operation. The gutta percha undergoes a further slight moulding to shape by body heat. After 2 months or so this temporary prosthesis is replaced by a hollow acrylic one made in a single piece with the denture (Fig. 67)

Facial palsy

In cases of facial palsy it was customary to support the angle of the mouth by an external splint composed of silver wire hooks into the mouth and over the ear fastened together by elastic. A more elegant method is to attach a small hook of acrylic resin to an upper denture or to a cap over a tooth so that the end of the hook just holds the corner of the mouth upwards and outwards.

INTERNAL PROSTHESES

Internal splints are occasionally necessary to maintain soft tissue alignment or to support grafts. Polythene has been mentioned in Chapter 10. It is a valuable material as an inlay in fashioning a depressed nasal bridge, and is particularly useful in a growing child, as it can easily be removed and replaced by a larger inlay every 2 or 3 years until growth ceases and a permanent repair is possible.

Lining of denuded cavities

Polythene tubes have been used to carry skin grafts for the lining of denuded cavities. However as the material is very inert, it was found that normal growth takes place around it. This discovery simplified several somewhat unsatisfactory procedures. In operations on the frontal sinus a polythene tube is left in the naso-frontal area (Fig. 68), and mucosa (or fibrous tissue) grows along and lines the channel in contact with the tube (Ellis, 1954)

Treatment of laryngeal stenosis

The same method (a development of Schmiegelow's procedure) has been employed in the larynx, instead of skin grafting, for the treatment of stenosis. After thyrotomy and excision of the scar tissue a large polythene tube is left in the larynx, anchored by a Kirschner wire passing through it and through the neck from side to side, transfixing and anchored on corks at each end. The tube is removed through the mouth after 3 or 4 months, and a smooth surface of regenerated mucosa, or of healthy scar tissue remains.

Mandibular replacement

The same principle has again been used after resection of the mandible. The bone is immediately replaced by a polythene or acrylic mould, or a plate of Vitallium, around which the tissues grow apparently unaffected by the inert foreign substance, which may eventually come to be buried in them. A denture can be supported on this living tissue covered inlay (Kazanjian 1939 Edgerton, Ward and Sikes, 1950)

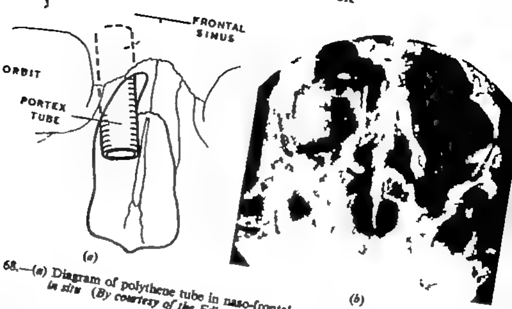


FIG 68.—(a) Diagram of polythene tube in naso-frontal area (b) radiograph showing tube *in situ* (*By courtesy of the Editor of the Journal of Laryngology*)

Replacement of pharynx and cervical oesophagus

The suppression of infection by antibiotics has immensely improved the "take" of skin grafts, and this knowledge has been applied in replacing segments of pharynx and cervical oesophagus A thick split skin graft supported on a rubber latex prosthesis (Fig. 69) is inserted between the divided ends of the pharynx. This method can be used as part of the repair after a radical surgical attempt at cure (Ready 1952) or as palliative treatment to relieve the ultimately complete dysphagia produced by a neoplasm. Dysphagia can also be relieved by a Souttar's tube—a tube made of coiled brass wire and shaped with a flange at the upper end. A lumen in the growth is created by dilatation and a Souttar's tube of appropriate size is forced through until arrested by its flange This tube remains *in situ* until the patient's death It immeasurably relieves discomfort even if it only drains off saliva, since the constant accumulation of saliva is not only a perpetual source of misery in itself but also an unnecessary cause of respiratory disorders and their accompanying miseries. Nutrition can be maintained by feeding through a gastrostomy

FIG 69.—Rubber latex prosthesis on which a sheet of thick split skin graft is draped to replace an excised segment of the pharynx.

The author has adopted this principle to maintain a lumen in a reconstructed pharynx and oesophagus when fibrous stricture develops A polythene tube with an expanded upper end is pushed through the stricture and impacted in it. The tube can be left in place indefinitely (nearly a year in one instance, and still without untoward symptoms or signs of any kind) and acts as an admirable lining. A similar type of polythene tube can also be used like a Souttar's tube to preserve a lumen in the tumour itself Whether a poly

thene tube will resist the continuing growth of the tumour is not certain but the material is tough and will stand a great deal of pressure

HEARING AIDS

All the modern operations on the ear fenestration stapes mobilization and tympanoplasty utilize magnification stimulating an enormous advance in the construction of and materials used in the manufacture of optical apparatus There has also been a great advance in methods of burring away bone (Chapter 8) But the development of hearing aids has been almost more remarkable The combination of the transistor with light and strong plastic cases and plastic electrical connexions and cables has resulted in instruments of minute size and

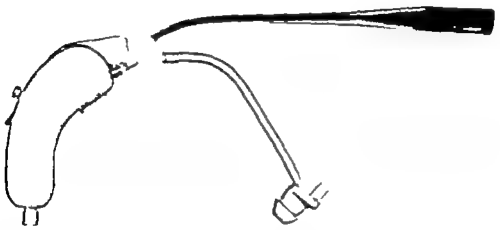


FIG. 70 —Ear clip hearing aid the thin polythene tube going over the pinna and into the meatal canal with an attached rubber latex insert arm of a pair of spectacles and its place of insertion in the instrument.

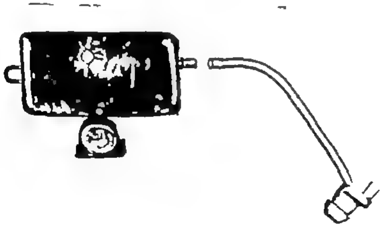


FIG. 71 —Hair clip hearing aid, showing where the mercury battery is inserted polythene tube and rubber latex insert.

high acoustic efficiency The ear clip aid (Fig. 70) is an indication of what is being achieved. The injection moulded plastic case lies behind the ear its position and comfort adjusted by the length of polythene tube entering the meatal canal, or it can be held more firmly by a small piece of cellotape, or fitted to the arm of a pair of spectacles The electrical portion of the earpiece is in the instrument itself and the insert in the meatus is of soft rubber latex Hair slide aids have been known for some time and a recent type is illustrated in Fig. 71 The case is fabricated of perspex, tortoiseshell cellulose acetate and is extremely light. It is clipped in a lock of hair in the depths of the coiffure in which the polythene tube and rubber latex insert are also hidden Again the acoustic portion of the earpiece is incorporated in the instrument itself The minute mercury battery has a life of 70 hours and costs two shillings These types of aid have an amplification of 35–45 decibels, a high fidelity reproduction, and are eminently suitable for all forms of conduction deafness, for certain cases of perceptive deafness, and for many cases of a mixture of the two

Hearing aids incorporated in the expanded arms of spectacle frames are already well known and newer designs are constantly appearing, combining the virtues of greater lightness and less bulk with improving acoustic fidelity

CONCLUSION

Surgical operations in the head and neck region may cause external disfigurement and also disruption of the food and air passages Repair of the first type of defect is often best achieved by prostheses of various materials rather than by reconstructive surgery Repair of the second type has utilized the principle that the growth of living tissue is apparently unhindered by the presence in bulk of certain materials. This is not a new principle, but its possibilities have only recently been successfully explored. It is easy to see that the further development of strong, inert, but more malleable materials, together with infection suppressing drugs of wider application will develop still more the surgery of this region

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CHAPTER 15

PRESERVATION OF TISSUES

LEON GILLIS

ALTHOUGH THIS BOOK sets out to describe materials which are employed in surgery the fact is that today preservation of natural tissues for subsequent grafting is becoming increasingly common and is essential for the advancement of modern surgery These preserved tissues are superior to artificial structures in the cases instanced below

METHODS OF PRESERVATION

The principle on which the methods of tissue preservation now rest was established by Carrel (1908 1912) He demonstrated that a variety of tissues, including skin and artery stored under liquid paraffin (Petrolatum) at ice box temperatures (between −1 C and +7 C) as a preservative medium " took as well as fresh tissues when subsequently grafted A variety of minor modifications in this basic technique have subsequently been introduced More recently some authorities on the basis of the results of tissue culture tests of explants of stored tissues have advocated the use of nutrient storage media such as dilute serum, in the presence of air (Peirce and his colleagues, 1949 Allgöwer and Blocker 1952) However for many tissues, and particularly skin the transplantation test of survival after storage is much superior to that of after tissue culture (Billingham 1954) Culture *in vitro* of small explants can only establish whether the cells remain alive if any of them grow out from the margins of the explants The transplantation test however will establish the survival of the tissue as a functional entity As Medawar (1954) has pointed out, it is possible to visualize a storage system which gives superlative results when the stored tissue is tested by tissue culture but which for some reason perhaps swelling and waterlogging of the ground substance may result in failure of a graft to " take Such a storage system would be clinically worthless storage systems must be appraised according to their success to make transplantation possible

The great drawback of all methods of storing tissues at ordinary refrigerator temperatures—that is, a few degrees above 0° C— is the progressive decline in the viability of the cells For skin the maximum storage life under these conditions is probably 6–8 weeks (Billingham 1954) and it is even less for other tissues

The fact that mammalian tissues will withstand freezing at temperatures far below the eutectic point of normal saline was established by the work of Mider and Morton (1939) and Briggs and Jund (1944) on skin—probably one of the most highly resistant tissues to thermal and other stresses in the body The cornea also is probably highly resistant on account of its exposed position in the body For example, continuous evaporation from the perpetually moist surface of the cornea must reduce its temperature considerably without apparent ill effects The important empirical discovery by Polge Smith and Parkes (1949) that pretreatment of

fowl spermatozoa with glycerol protected them against the otherwise fatal effect of rapid freezing has opened up the possibility of the long term storage of a variety of other cells and tissues It has since been established that after pretreatment with a physiological saline solution containing 15 per cent glycerol a variety of cells and tissues, including erythrocytes endocrine tissues, and skin may be frozen and preserved for prolonged periods at very low temperatures, in what is effectively a state of suspended animation." Rabbit-skin grafts stored at −79° C for upwards of a year following glycerol pretreatment, showed no trace of deterioration after they had been thawed rapidly and transplanted back to the animals from which they had been removed initially They behave in all respects like grafts of freshly excised skin Grafts impregnated with Ringer's solution *without* glycerol and before the days of deep-freeze storage gave inferior results. Glycerol is completely non toxic even isolated epithelial cells of skin survive a brief exposure to 98 per cent glycerol

It should be emphasized that all workers who have studied the viability of any tissue after freezing and thawing are agreed that *slow* freezing is preferable to rapid freezing and *rapid* rewarming or thawing is essential To some extent glycerol pretreatment protects tissues against the otherwise harmful effects of rapid freezing and slow thawing The biophysical aspects of freezing living cells and the mechanism of the protective action of glycerol have been investigated by Lovelock (1954)

There are good grounds for believing that means can be devised to store many tissues and cells at very low temperatures for long periods without progressive deterioration of viability

For homografts of those tissues that do not have to be viable at the time of transplantation, preservation presents no serious problem Although storage in the frozen state at low temperatures is perfectly satisfactory and is in common use, it is likely that freeze-drying will be the method of choice in the future for these tissues The superiority of the freeze-drying method lies in the fact that once the moisture content has been reduced below about 1 per cent, tissues may be sealed off under vacuum and stored or transported perfectly well at room temperature for long term storage it is by far the cheaper and more convenient method

STERILIZATION

Sterilization of contaminated donor material in the case of homografts which need not be alive at the time of transplantation presents no particular problem Chemical treatments are not contra-indicated as long as they do not cause either denaturation of the proteins or structural changes For example bone and cartilage grafts may be sterilized with aqueous solutions of merthiolate and frequently they are actually stored in such solutions in the refrigerator freeze-dried blood vessel segments and other freeze-dried tissues are sometimes sterilized with ethylene oxide gas.

SKIN STORAGE

Refrigerated skin grafts

In the routine examination of stored skin grafts it was noted that some of the samples discarded because of age but with the original seal intact, had an offensive

odour This did not appear to be due to necrosis and on bacteriological examination the samples proved to be grossly contaminated This observation became the basis for routine culturing of skin grafts The cultures are taken from both "surgically clean and "surgically dirty cases and a culture follow up is done on all the samples It should be noted that it is practically impossible to make skin even hair free skin on the palms and soles absolutely sterile

Methods of study

During a 2 year period without special selection cases in which skin grafting was required were utilized in this study In both surgically clean and surgically dirty cases, samples of skin were taken in the operating room at the time of the definitive surgical procedure All the donor areas were washed with soap and water then cleaned with ethyl alcohol (70 per cent) and phemerol Skin grafts were taken with a Padgett Hood dermatome and two samples of skin were immediately cut off One was placed in a sterile petri-dish for culture the other was wrapped in a saline moistened sponge, placed in a glass tube plugged with cotton or a cork and sealed with liquid paraffin The tubes were labelled with the patient s name and the date and were stored in an ordinary refrigerator (3 –5° C) Twice at 3-week intervals these samples were opened under sterile conditions and specimens were again taken for culture In some cases 9 week cultures were made, but these yielded no further information

The samples used for culture were minced with sterile saline solution and the mixture was then used to inoculate a tube of thioglycolate broth and a chocolate agar plate Colony counts and bacterial identification were made by the department bacteriologist. The cultures were incubated and observed at 24 48 and 72 hours.

Summary and conclusions

One hundred samples of skin have been cultured 38 were from " surgically clean " cases and 62 from surgically dirty" cases Of the samples 18 (36 8 per cent) from the former group and 34 (54 8 per cent) from the latter reacted positively on initial culture The take " of the skin grafts was good (95 per cent or better) in all but 3 cases and these were dirty " cases in which proteus organisms were combined with non-haemolytic *Staphylococcus aureus* As noted above it is difficult, if not impossible to sterilize the skin even in " clean " cases by routine surgical preparation, but bacterial contamination by itself is not the usual cause of graft failure. In the " dirty " cases, an increase in the number of initially positive cultures was out of proportion to the number of those cases (6 per cent) in which the grafts were taken from areas adjacent to open wounds In 10 instances in which direct skin swabs gave negative results on culture, samples of skin still yielded positive cultures. It is suggested that there is a pooling of bacteria in the skin similar to that observed by Price (1938 *a* and *b*) in the spleen, even when cultures of the blood are negative Cultures of the skin may thus be helpful in evaluating the bacteraemia of the extensively burned patient.

removed within 10 hours of death and stored under these conditions consistently proved to be satisfactory for full thickness and lamellar grafts

The success of this particular method of storage and the increased availability of corneal tissue has made it possible to establish eye banks throughout Great Britain

One additional advantage of liquid paraffin as a storage medium is the protection which its high viscosity affords to donor eyes against mechanical damage during transit

Storage in the frozen state

The work of Smelzer and Ozanics (1946) is frequently cited as evidence that the storage of untreated donor eyes or corneal grafts, at very low temperatures is unsuccessful These authors froze freshly excised rabbit donor eyes *rapidly* to −196° C by immersion in liquid nitrogen and after storing them at this temperature for various periods up to 4 days, allowed them to thaw out at room temperature—that is, *very slowly* So far as skin is concerned this method would be unquestionably fatal to its cells and it is therefore, not surprising that though the grafts are reported as having healed in satisfactorily they soon became oedematous and opaque Before the possibility of storing untreated corneal tissue at very low temperatures can be excluded however it will have to be shown that grafts, frozen and thawed at the optimum rates—that is, slow freezing and rapid thawing—fail to remain clear on transplantation

The beneficial effects of pretreating various mammalian tissues with dilute glycerol solutions before freezing and storage at very low temperatures have been described above. Eastcott and his colleagues (1954) have applied this method to corneal grafts of different thicknesses. After excision from cadaver eyes, they were treated with a 15 per cent solution of glycerol in Ringer s solution for 1 hour before being frozen to −79° C at which temperature they were stored When required for transplantation thawing-out was rapid in all cases Satisfactory results were obtained with lamellar grafts preserved for several weeks The authors stated that these grafts in their post-operative behaviour differed in no respect from fresh grafts Less satisfactory results however attended the use of stored full thickness grafts

At the East Grinstead Regional Eye Bank, in collaboration with Dr Giles Romanes, similar studies have been carried out In addition workers at East Grinstead have investigated the possibility of preserving the whole donor eye to allow the surgeon greater freedom in employing his stored material On receipt of a donor eye or cornea at the eye bank, it is removed from the paraffin solution in which it was transported, thoroughly rinsed with normal saline to remove all traces of adherent paraffin and a culture is taken The eye is then completely immersed for 20 minutes in an antibiotic solution (*see* below) after which it is transferred to excess 15 per cent glycerol in Ringer s solution at room temperature for 1 hour to ensure that the cornea is thoroughly impregnated by the glycerol All fluid is then drained off and the eye is placed with its cornea uppermost in a wide-mouthed shallow glass phial which is lagged with gauze to prevent rapid freezing. This phial is then placed in contact with solid carbon dioxide (dry ice and Drikold are synonyms) at −79° C in the deep-freeze bank. This consists of a large, well-lagged 5-gallon Dewar flask, containing solid carbon dioxide as the

refrigerant. It will house up to 30 eyes The refrigerant is cheap and readily available—a 16-pound block will maintain the bank for about a fortnight.

When a donor eye is required the phial is withdrawn with protected hands, from the bank and its cap quickly removed. The eye (or at least its cornea) is then thawed out rapidly by pouring in excess normal saline or Ringer's solution, heated to body temperature and as soon as the ice holding it to the bottom of the phial has thawed the eye is tipped into a bath of warm saline Before thawing, the frozen cornea is grey and mottled and the eye brick hard, but, on thawing, the cornea rapidly resumes its normal transparency and the white and opaque frozen lens can be seen through it The lens, being more isolated from the source of heat than the cornea, takes about 10 minutes to thaw out completely As the eye reaches body temperature minute air bubbles frequently appear in the corneal stroma and its epithelium may be separated from it. On cutting the cornea, it seems to be more rubbery in consistency than those of eyes preserved at temperatures just above freezing point, but the transparency is better and experience shows no progressive deterioration on storage.

Experience so far indicates that while it is possible to obtain some permanent transparency with full thickness grafts stored for many months by this deep-freeze method, the behaviour of these grafts is not entirely satisfactory Their shortcomings are of an optical nature and may be attributed to factors such as folding and retraction of Descemet's membrane and separation of the corneal lamellae, possibly by the formation of the air bubbles seen on thawing. Good results have, however been obtained with lamellar grafts from eyes stored for as long as 3 months.

The anomalous behaviour of full-thickness grafts preserved in this manner may be attributable to the death of an appreciable portion of their cell population or perhaps though the majority of cells may survive irreversible changes which are responsible for the optical imperfections may have occurred in the arrangement of the lamellar fibres. It must be borne in mind that the clinical test of permanent transparency and optical perfection is more exacting than any test to which preserved grafts of any other type of tissue are submitted

At the present state of knowledge it must, therefore be emphasized that the problem of the long-term preservation of corneal donor material, at very low temperatures, still awaits a satisfactory solution The results of the preliminary trials conducted by Eastcott and his colleagues (1954) may be said to hold out reasonable hope that the principle of the method may be sound.

The viability of deep-frozen grafts.—From our knowledge of other tissues there is a *prima facie* case for assuming that at least some of the cells in a corneal graft may be alive after storage at $-79°$ C following glycerol pretreatment. To some extent this case is reinforced by the excellent clinical results obtained with stored lamellar grafts. Before deep-frozen grafts were used clinically at East Grinstead trials were carried out to determine whether the epithelial cells of thin shavings of rabbits corneas—essentially lamellar grafts in their constitution—were still alive after a month's storage in this manner The test of viability comprised grafting the thawed-out shavings in "open style" to extensive vascular beds cut in the skin of the animals from which they had been removed initially The amoeboid projection of the epithelial and corneal cells on the surface of the margins of the graft left no doubt that a high proportion of the epithelial cells had survived

Evidence that guinea pig corneas after storage in a similar manner contain surviving cells has also been established by Bacsich and Wyburn (1954)

Assessment of the suitability of stored corneal tissue

There is no simple obvious criterion for assessing the suitability of stored corneal graft material Buschke (1951) has given a number of criteria that various authors have proposed but as he pointed out even evidence of viability does not necessarily imply the presence of the morphological and functional integrity requisite for a successful take and for the maintenance of transparency At present there is no better criterion for clinical purposes than visual experience in deciding whether corneal tissue is, or is not suitable for the provision of a graft A suitable donor cornea is of normal shape and has normal curvature it has a bright surface sheen but it may be mottled and grey in colour it must not be swollen and should show firm consistency when cut The presence or absence of epithelium is immaterial since its loss is speedily made good from the host Obviously soft or macerated corneas are useless and there must certainly be no opacity necrosis, smell, or fungal growth

Factors governing the selection of donor material

In theory and in practice the ideal donor eye is that which is used immediately after surgical excision from a living person but Russian surgeons have expressed the view that some period of preservation may be an advantage Second choice is an eye which has been removed as soon as possible after death—10 hours is a prudent upper limit. The corneas of adults are preferable because of their relative rigidity and physical uniformity

Transport of donor material

Where an eye bank supplies a large area, a robust transport box is necessary to protect the donor material in transit. The simple arrangement which has been in use for some years at East Grinstead Eye Bank comprises a stout wooden copper-lined box in the bottom of which is fixed a brass clamp securely holding a wide mouthed stoppered glass bottle the bottle is half filled with liquid paraffin To keep the eye cool, the box is filled with ice before despatch to the eye bank. Sterile glass containers are maintained in readiness at the various hospitals serving the eye bank and the donor eyes on removal are stored temporarily in the hospital refrigerator pending the arrival of the transport box from the bank A similar contrivance has been described by Fowler (1953) In principle it consists of an insulated jug wherein the eye is safely held in a moist chamber This has proved adequate for the transport of eyes over long distances in the United States of America.

The bacteriology of the donor eye

The bacteriological examination of the donor eye has become of particular importance with the increasing use of cadaver material Although the possibility of transmitting disease by a corneal graft is so remote that it can be dismissed the question of external contamination and infection of a cadaver graft is highly important The bacteriological examination of cadaver donor eyes is a routine procedure at the East Grinstead Eye Bank Recent records show that 34 cadaver eyes in 218 routine culture examinations were infected with pathogenic organisms The organisms, of which many were penicillin resistant were *Staphylococcus*

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aureus haemolyticus (23) *Pseudomonas pyocyanea* (4) *Streptococcus viridans* (5), and *Escherichia coli* (2) Only one grafted eye in over 100 full thickness grafts was lost from infection (this was due to *E. coli* and the graft had come from a cadaver donor)

Abdin (1952) carried out bacteriological examinations of the conjunctival sacs of 100 cadavers at the Kasr-el Aini Hospital—direct smears and cultures were taken between October and November In 198 smears 58 were negative, but only 9 were negative on culture The saprophytic organisms in positive cases were *Staph albus* or *Bacillus xerosis* or both. Pathogenic organisms occurred in 39 smears and 76 cultures the organisms were *Staph aureus* Morax Axenfeld bacillus *Neisseria gonorrhoeae* or Koch Weeks bacillus The significance of these results to the use of cadaver donors for corneal grafts was emphasized *It must, therefore be realized that cadaver eyes are a potential source of infection and present a very real danger which must be appreciated and controlled if this source of donor material is to be safely and widely employed Present methods of pre*servation do not destroy micro-organisms

The bacteriological control of cadaver donor material

At the East Grinstead Eye Bank the following routine prophylactic measures have been adopted when acquiring cadaver material A culture is taken of the cadaver conjunctiva and the eyes are thoroughly irrigated with penicillin solution before they are removed The excised eyes or corneas are then placed in sterile liquid paraffin containing an emulsion of penicillin and streptomycin (100 units of each per gramme of liquid paraffin) On arrival at the eye bank a culture is again taken of the donor eye prior to storage by one of the methods already described. The results of the cultures are available to the surgeons before operation and any eyes which have produced positive cultures are not used on patients but are discarded to use in teaching

For eye grafts as with grafts of any other tissue, careful aseptic measures in their procurement is the ideal Unfortunately with cadaver material this ideal is not easily realized. Undoubtedly the prevention of contamination must be the objective to ensure the sterility of material to be used in corneal graft surgery rather than any method of sterilization A final assault on the possibility of graft infection is made by washing the material in 1 per cent Cetavlon immediately prior to use in the operating theatre

BONE STORAGE

With the wider scope of orthopaedic operations the necessity of using homogenous rather than autogenous bone grafts is becoming increasingly necessary

There is no doubt that the use of bone other than autogenous obviates for patients, and particularly children who may be subjected to frequent grafting operations the trauma of a second operation

In recent years two methods of preservation of bone have been generally used. In one the bone is preserved by refrigeration, and in the other the bone is preserved in a solution of merthiolate When rapidly frozen by "deep-freeze" methods bone can be utilized for grafting up to some 3 months or so from the time it has been acquired

The bone bank

The necessary requirements for the establishment of a bone bank include (1) scrupulous aseptic technique in obtaining bone for example from amputations or resection of bone (2) sterile containers (3) laboratory facilities for cultures (4) storage facilities, and (5) an indexing system

Bone supply

There are three possible sources of bone (1) Bone from amputations following, for example trauma, diabetes mellitus, or arteriosclerosis (2) surplus bone from auto-grafting procedures and (3) bone from cadavers Generally speaking, it is bone taken from amputations that is used for grafting.

It is important to ascertain that the donor s Wassermann reaction is negative and that rigid aseptic technique is observed in cutting up the bone Areas of localized infection or dry gangrene are excluded from the operation field with dressings before the donor reaches the operating theatre and the dressings are left on Amputation limbs from patients with conditions such as wet gangrene or spreading infections must not be accepted

The limb to be amputated receives a complete skin preparation and any areas where skin breakdown has occurred are protected by several thicknesses of sterile gauze and, when the amputated limb is set aside on a sterile table, resection of the available bone is carried out as soon as possible by a second team. Skin towels are applied to a long incision which is made down to the subcutaneous surface of the tibia or other bone and all the soft tissues are separated subperiosteally Using an electric saw suitable sizes and shapes of cortical bone grafts are cut, and all cancellous bone is carefully curetted and put in separate containers

The containers

These should be double jars made of glass with metal screw tops to each jar They are assembled in large numbers autoclaved and kept in readiness adjacent to the operating theatre When the bone has been packed into the inner jar the outer jars are numbered with glass pencils A specimen is taken from a piece of bone and placed in the correspondingly numbered tube of culture medium The full jars are stored until the bone, on which there must be a negative culture report, is required for use

Storage

Low temperatures prevent sepsis and bacterial growth and preserve the physical and chemical properties of bone unaltered The plasma freezer which most hospitals possess maintains a constant temperature of 4 5° C (40 F)

Culture control

Fresh thioglycolate medium is useful since it provides both aerobic and anaerobic conditions. The selected specimens of bone are incubated for 48 hours before examination If a specimen yields even one positive culture then it should be discarded

Indexing

The index cards should show the donor's history and proof that there has been no recent generalized infection, no positive Wassermann reaction, and no evidence of malaria or jaundice.

When bone is required, the appropriate size and shape and type is selected and allowed to thaw at room temperature. When bone is used the appropriate card is completed and a permanent record of all bank-graft procedures is thus obtained.

Merthiolate bone banks

Morgan, Jamieson and Powell (1933) reported the use of merthiolate solution as preservative. O'Connor (1939) and Brown and DeMere (1948) preserved cartilage in merthiolate.

Alternative procedure

An amputated limb is wrapped in a sterile towel and within 6 hours is taken to the theatre and under full sterile conditions all the soft tissues are removed, the bone split down its centre, a culture taken from the bone marrow, and the bone put into a 1/1 000 solution of merthiolate, all bone being covered. Two weeks later again under sterile conditions, the bone is taken out of this solution, further soft tissue removed and a further culture taken. The bone is then put into a fresh container of 1/5 000 solution of merthiolate. Thereafter cultures are taken at approximately 6-week intervals until all the bone is used, or discarded at the end of 9–12 months.

Bone has been used up to 1 year after being put into the bone bank, but on the average it has been used in 3–4 months. This method is simple, economical and requires little maintenance.

Merthiolate preserved bone in the form of chips gives good results. Massive preserved bone grafts are still dense and unvascularized in many cases after more than a year; non-union is not infrequent and sometimes late fractures occurred.

Experiences show that this type of preserved bone is of real value in augmenting bone grafts, preferably in the form of mixed autogenous and merthiolate preserved chips. Uniformly good results are obtained, particularly in the obliteration of bone cysts. The incidence of infection (7.2 per cent) is rather high, but it is hoped that the use of the stronger solution of merthiolate (1/1 000) throughout the period of storage will reduce this.

THE STORAGE OF ARTERIAL GRAFTS

Bank storage

The first satisfactory arterial bank was that of Gross, Bill and Peirce (1949). In this bank grafts were stored in 10 per cent homologous serum at 4° C. They had a life of up to 6 weeks, and because of this there was a high rate of wastage. Hufnagel (1947) and Hufnagel and Eastcott (1952) have described the technique of freezing and storage at low temperature and Marrangoni and Cecchini (1951) introduced the method of freeze-drying. Rob (1954) has also described the use of lyophylized grafts in Great Britain. This method has the advantage that the storage is at room temperature and the grafts are easily transported. On the other hand, the process is a complicated one and the practical advantages of simplicity enjoyed by the alternative techniques are considerable.

Heterologous grafts were used successfully in animals by Carrel (1908) but their use in man is still in an experimental phase Hufnagel (1954) has reported the successful use of such grafts sterilized in liquid ethylene oxide and then frozen and dehydrated If such a technique can be shown to be safe, the availability of suitable grafts will be vastly increased and the task of keeping an ample stock of grafts in the bank will be eased

Homologous arterial grafts are taken in the mortuary from a person under the age of 40 years who has died usually as the result of an accident The grafts are tested for transmissible disease, and taken within 12 hours of death with full aseptic precautions They are cut into suitable lengths placed in sterile Pyrex tubes and a sterile rubber bung is inserted The sterile part of the operation is now completed A freezing mixture is prepared by adding carbon dioxide snow to methylated spirit until a temperature of about −70 C is recorded on an alcohol thermometer The Pyrex tubes are inserted into this mixture in turn for about 3 minutes. At the end of the 3 minutes the grafts are transferred to the bank for permanent storage This may consist of a commercial deep freeze operating at about −20° C, as used by Deterling, Coleman and Parshley (1951) An alternative is an insulated box kept cold with blocks of carbon dioxide snow which need to be replaced about twice a week to maintain a temperature of −79 C This has the advantage that it is not dependent on a constant electrical supply and will not warm slowly in the event of a power failure

When a graft is required the selected tube is taken to the theatre the bung is removed and the tube filled with saline solution at 37 8 C (100 F) As the graft floats free it is poured into a bowl of warm saline It is immediately ready for ligation of its branches and insertion into the defect If it is necessary to transport a frozen graft to another hospital it can be done in a wide mouthed vacuum flask packed with carbon dioxide snow

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CHAPTER 16

NATURAL MATERIALS

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SUTURE MATERIALS

THE CHOICE of suture materials, as of so many other things in surgery and outside it, has often been governed more by fashion than by the result of controlled scientific experiment Modern trends if any trends may be discerned in a practice subject to so many variations in different countries, and between individual surgeons even in a single hospital have been toward the substitution of non absorbable for absorbable materials for most surgical sutures and ligatures and more recently toward the use of plastic and metallic filaments rather than the "natural" materials which until recently held the field The relative merits of absorbable and non-absorbable materials, the importance of the Halsted "silk" technique in the use of the latter and the differences in the reactions of the tissues to these differing materials are discussed elsewhere in this volume This section aims merely to set out for the surgeon the various materials which are available for his choice, their physical properties and the sizes and forms in which they may be purchased Some knowledge of their design their mode of manufacture of sterilization, and of the differences between different products sold under similar names should help him to select intelligently the material best suited to his specific purpose and to accept with a properly critical reserve the claims that may be made by enthusiasts for any particular "new" suture or ligature material.

To avoid confusion and to gain in brevity the word "suture" will be used in this section to refer to any thread, strand or cord used for any surgical purpose. In practice, of course, a "suture" is a strand used threaded on a needle to approximate tissues, while a "ligature" is a strand used to tie off blood vessels for haemostasis.

ABSORBABLE SUTURES

Catgut

Catgut is the only absorbable suture now in common use The earliest reference to it appears to be in the writings of Galen, who used hemp and silk cord for ligating bleeding vessels, but suggested the use of catgut when these were not readily available

Surgical catgut is a development of the musical string Its name is usually accepted as being a variant of "kitgut," the "kit" being a small three-stringed violin in common use in the sixteenth century and earlier Its origin has always been the gut of the sheep and not that of the cat. Surgical gut is prepared from the submucous layer of the proximal third of the small intestine of the sheep The gut is cleaned split into ribbons, and from these ribbons the inner mucous lining and the outer sero-muscular coat are removed mechanically leaving a thin, strong network of fibres consisting chemically of almost pure collagen From one to five of these ribbons are then stretched and mechanically twisted together under

controlled tension to form the catgut thread. The threads are then dried separately under tension polished, gauged for size, heat-sterilized, and packaged in hermetically sealed tubes

Sterilization

Earlier textbooks of surgery usually devoted a section to the methods of sterilization of catgut, and the multiplicity of methods which have been suggested is testimony to the complexity of this important problem Chemical sterilization has all too often proved unreliable especially in the destruction of tetanus spores, and adequate heat sterilization (which to prevent denaturation has to be done with the gut in a dehydrated state) is only really practicable in large scale commercial plants The marketing of catgut in non-sterile hanks or reels for sterilization in individual hospital theatres has now therefore, and rightly become an outmoded practice no surgeon need these days be tempted into sterilizing his own catgut. After sterilization the gut, nearly always in individual glass tubes, is immersed in a fluid which preserves the tensile strength and smoothness of the thread, and sealed

Boilable and non-boilable catgut

Not every medical student on graduation and not every theatre sister seems to have been taught the significance of these terms, and to appreciate that they apply not to the catgut but to its container The difference between the two lies in the composition of the tubing fluid. "Boilable" gut is catgut still in the anhydrous state packaged in an anhydrous tubing fluid, usually xylol. The surface of the tubes may therefore, be sterilized by boiling or autoclaving without damaging the quality and tensile strength of the catgut within Such anhydrous gut is, however difficult to handle, and must be soaked in water for several minutes before it is pliable enough for use. It is, too consistently weaker size for size, than non-boilable gut and it is used little or not at all by most surgeons.

"Non boilable" gut is partially rehydrated after sterilization and is tubed in an alcohol–water mixture which has a plasticizing or softening effect upon the catgut. Such tubes however must not be sterilized by heat or the catgut will be spoilt The tubes are stored in sterilizing fluid and the suture is pliable, ready for use as soon as the tube is open.

Plain and chromicized catgut

Catgut became the suture material of choice in the early days of surgery precisely because it was "absorbable" Plain untreated catgut is very rapidly digested and destroyed by the tissues—usually within 4–7 days if implanted into muscle and much more rapidly in peritoneum or mucous membrane. It is of little use as a suture required to hold tissues in apposition until soundly healed, but is the ideal absorbable haemostatic ligature for small and medium sized vessels where the integrity of the ligature is only important for a few hours or days while clot is forming and organization taking place

Various methods of treating the catgut to make it harder and more resistant to tissue digestion have been suggested Only one the chromicizing process, has come into general use Chromicizing is usually carried out while the gut is still in the ribbon stage before spinning. A much more uniform, complete hardening of the thread is obtained in this way than by surface chromicizing. The degree

of hardening of the thread can be controlled by varying the time of treatment Until recently manufacturers have produced several different grades of catgut labelled 10 day 20 day 40 day and so on according to the time taken for absorption when buried in muscle tissue Surgeons using catgut so labelled should be clear (*a*) that times so designated are so approximate as to be totally unreliable (*b*) that absorption in serous or mucous tissue will be from three to four times as rapid (*c*) that absorption is progressive and effective tensile strength is lost many days before absorption is completed

In the United States of America, as a result of the recommendations of the *United States Pharmacopoeia* Revision Committee the practice is gaining ground of marketing four grades of catgut, specified as follows

Type A Plain unchromicized gut.
Type B Mild chromic
Type C Medium chromic, retaining half its tensile strength for about 20 days
Type D Extra chromic, retaining half its tensile strength for about 40 days.

It will be noted that the specification is "retaining half its tensile strength" and not "absorbed"

These times of absorption take cognizance of the fact already noted that absorption is a gradual process, and that effective tensile strength is lost long before the gut is completely absorbed Howes and Harvey (1929) made accurate estimations of the rate at which tensile strength decreased when catgut of different sizes and qualities was implanted in the body Some of their results are shown in Fig. 60 which is simplified and abbreviated from their article.

Two other points of practical importance brought out by Holder (1946) in his study of the properties of catgut are that a thick strand loses tensile strength just as rapidly as a fine one and a single strand lasts just as long as a double one

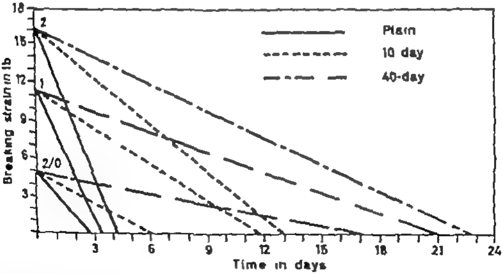

FIG 72.

Size and tensile strength

These are properties which go hand in hand though the relationship between them is by no means a simple one In general for any particular material the tensile strength is directly proportional to the square of the diameter of the thread

Tensile strength is usually expressed in terms either of " straight pull " or " knot pull "—the minimum weight required to break respectively a straight filament and a knotted thread As the tying of a knot inevitably produces some fraying and cracking of the strand knot strength is always less than straight pull strength, usually in the ratio of about 7 to 10 Douglas (1949a) has shown that in actual practice so far as surgical sutures are concerned a more relevant and useful measure would be the breaking strain of a knotted loop such as ordinarily constitutes a suture holding tissues in apposition This is always considerably greater than the strength either of a straight thread or a knotted one, and indeed approximates to the sum of these two This is a property of considerable importance in the selection of the size of suture for a specific purpose for there is no advantage, and often considerable disadvantage in using suture material of a tensile strength greater than that of the tissues it has to hold together

Partipillo (1953) pointed out that few tissues have a greater tensile strength than that of 3/0 catgut The holding power of fat is virtually nil of small bowel less than 1 pound of peritoneum a little more of muscle up to 3 pounds and only in fascia and similarly condensed connective tissue layers is the holding power of the tissues greater than the tensile strength of number 3/0 catgut Number 0 type C chromic catgut, having a minimum tensile strength of 7 pounds has more than the required strength for suturing fascia. This is an important point, for there is no doubt that in the past much coarser strands (both of catgut and of silk) have been used than is either necessary or desirable and the surgeon should *seek to choose a size of suture which is as small as is compatible with the holding* strength of the tissues with which he is dealing. Finer sutures cause less tissue reaction and permit more accurate apposition of the tissues

The sizing of catgut and its expression in terms of a numerical series is a subject on which uniformity and standardization have still to be achieved. British made catgut is issued in serial sizes from 7/0 to 7 and statutorily defined standards are laid down which must be adhered to by all manufacturers under the terms of their

TABLE I

MINIMUM BREAKING LOADS FOR BRITISH-MADE CATGUT

Size	*Diameter in mm*		*Min breaking load in lb*	
	Min	*Max*	*Straight pull*	*Over knot*
7/0	0·025	0·064	0·25	0·125
6/0	0·064	0·113	0·5	0·25
5/0	0·113	0·179	1	0·5
4/0	0·179	0·241	2	1
3/0	0·241	0·318	3	1·5
2/0	0·318	0·406	5	2·5
0	0·406	0·495	7	3·5
1	0·495	0·584	10	5
2	0·584	0·673	13	6·5
3	0·673	0·762	16	8
4	0·762	0·864	20	10
5	0·864	0·978	25	12·5
6	0·978	1·105	30	15
7	1·105	1·219	35	17·5

nce In diameter it is required (Martindale 1952) that not less than 32 dings out of 48 made upon two strands taken from any one batch must be hin the limits of Table I and the remaining 16 readings within the limits given one gauge greater or smaller than that stated In tensile strength the require nt is that " the average breaking loads of 12 strands taken from any one batch ermined on the straight pull and over a surgeon s knot are not less than the nimum breaking loads (see Table I) for the gauge stated on the label

The sizes and strengths of American manufactured catgut used formerly to fer considerably from those of the British product However since the twelfth ision of the United States Pharmacopeia (1942) the standards laid down proximate closely to the British The sizes of non boilable catgut are identical th those of Britain the maximum diameter prescribed for " boilable " sutures limited to 80-88 per cent of that of the non boilable Tensile strength on aight pull is the same, gauge for gauge as the British but the values given to knot strength are slightly higher For all practical purposes now however rgeons using both British and American catgut may employ the same sizes for her product

bbon gut

For special purposes catgut is supplied in ribbon form and can be obtained th plain and chromicized The ribbon is usually ⅛ inch wide and 18 inches ng. It is usually packaged as a boilable suture in an anhydrous preservative bing fluid and whether the tube itself is sterilized by boiling or by chemical eans the strand requires to be soaked in sterile saline for 10 to 15 minutes to come pliable enough for use It can be had ready swaged to atraumatic needles.

ngaroo tendon

This is the only absorbable suture other than catgut which has come into any ing like general use, and even this has very little application in present-day rgery It is prepared from the individual tail tendons of the small kangaroo engths vary from 10 to 18 inches Kangaroo tendon swells considerably more an catgut after implantation in the tissue so that care must be taken not to tie nots too tightly The only reason for using kangaroo tendon is its very high nsile strength even the finest strands having a breaking strain of 28 pounds or ore.

NON-ABSORBABLE MATERIALS

the last two decades there has been a marked swing towards the use of non sorbable materials for most sutures and ligatures The arguments for and gainst this practice are discussed elsewhere in this book As in so many other elds there has been an increasing tendency to the replacing of natural substances y synthetic products of more uniform properties the relative merits of the two e not discussed in detail in this chapter but it may fairly be said that most of the nthetic substances so far produced have certain disadvantages and that natural lk and cotton will continue to be widely used for a good few years to come This eing so surgeons should have a clear idea of their properties and what they will nd will not do

ilk

Silk is derived from the continuous threads spun by the species of caterpillar opularly known as the silkworm The thread is spun by the caterpillar by the

excretion of a heavy viscous fluid which forms a thread on exposure to the air The thread is used by the insect for the formation of the cocoon, and is obtained for use by the unravelling of this cocoon The natural threads consist essentially of a core of fibroin with a covering of sericin or silk albumin, and some covering materials. The silk as used for manufacturing surgical thread consists of almost pure fibroin, a protein allied to keratin the outer layer being removed in the process of manufacture. It is insoluble in water alcohol or ether but is readily dissolved by strong alkalis or mineral acids

Silk is usually used as a plaited or braided thread Chinese twist is a special form of particularly high tensile strength which is prepared by twisting silk floss in a solution of gelatin or glue. The braided silk if untreated, takes up considerable quantities of tissue fluid, so that most surgeons now prefer "non-capillary" silk which is processed to make it less absorbent. Such treated silk has a considerably lower coefficient of friction than has the "natural thread, so that secure knots are not quite so easy to tie Nevertheless serum-proofed silk is still so much easier to tie securely and much less likely to slip than is catgut of a similar calibre that this remains one of its principal advantages.

Size

American manufactured silk like most other American non-absorbable sutures, is now numbered from 7/0 to 7 in the same gauges as are used for catgut In Great Britain unfortunately uniformity of numbering for non-absorbable sutures has not yet been agreed upon and surgeons will find great confusion and disparity in the numbering of different materials. At present, for instance the diameters of No 1 nylon, silk and catgut respectively are 7 9 and 23 thousandths of an inch while for metallic sutures the Standard Wire Gauge is usually employed and adds further to the confusion Douglas (1949b) has suggested the numbering of all sutures in thousandths of an inch (0 18 0 2 and 0 58 millimetre) or alternatively numbering according to the accepted standards for catgut

Table II shows the approximate correspondence between *B P* catgut sizes and the numbers usually applied to surgical silk To save repetition of the table the corresponding numbers for cotton, which is discussed below are included in the one table.

Tensile strengths

For strands of equal diameter the tensile strength of braided silk is usually slightly less than that of catgut. It is important to realize that the tensile strength is considerably diminished by boiling, and it is best sterilized by saturated steam at 250°–260° F for 20–30 minutes. Most silk will withstand 2 or 3 sterilizations by this method without appreciable loss of tensile strength It should be noted that silk contracts on heating, so that if it be sterilized in spools that are at all tightly wound, it may be so stretched as to lose its tensile strength.

While the subject of the fate of suture materials after implantation in the tissues is not specifically dealt with in this chapter it should be noted that although silk is universally regarded and classified as a "non absorbable" suture, it should not be assumed that it retains its tensile strength indefinitely Some careful work by Douglas (1949b) has shown that, contrary to popular belief silk and other natural sutures undergo a progressive loss of tensile strength Douglas tested three types of silk suture—No 0 and No 2 unproofed and No 1 proofed

TABLE II

COMPARISON OF CATGUT SILK AND COTTON SIZES

Catgut	*Silk*		*Cotton*
	Plaited	*Twist*	
5 0	2 0	4 0	80
4 0	0	3 0	70
3 0	1	2 0	60
2 0	2	0	50
0	3	1	40
1	4	2	30
2	5 and 6	3	20
3	7 and 8	4	12 and 16

Unproofed silk, independent of the size of the thread had lost up to 80 per cent of its tensile strength by the end of 2 months, and after 4 months was so weak that it broke into fragments on being removed from the tissues "Serum proofed silk retained its strength rather longer but even this after 4 months retained only 30 per cent of its original strength

Silkworm gut

This once popular suture is now relatively little used partly because of certain disadvantages and partly because good quality gut has become difficult to obtain Most of the best gut manufactured in Spain is now claimed by fishermen and surgeons have to do with a poor quality material It is prepared from the silk worm larvae *before* the cocoon is spun The larvae are killed and the glands pulled out by hand into threads These are of course monofilamentous and tend to be thinner at one end than the other Threads vary from 12 to 18 inches in length and are graded into extra fine fine, medium coarse and extra coarse The threads are brittle and not very easy to handle. They are however smooth and hence easily removable as tension sutures quite inert, and non-irritating to the tissues The thread withstands boiling, but alkaline solutions rapidly destroy its tensile strength The tensile strength is of the same order as silk of comparable diameter but owing to its brittleness the "knot strength" is considerably less.

Cotton

Cotton thread is formed by the spinning of the fine cellulose fibres of sea island or Egyptian cotton Microscopic examination of individual hairs" which are formed by the growth of a single epidermal cell of the seed case of the plant shows that they are twisted and flattened This is of considerable technical importance as the natural twist facilitates spinning and produces a thread which is less likely to fray out than silk or linen the fibres of which have no natural twist.

Cotton thread is available as "ordinary" cotton which is a 6-ply thread and as *mercerized cotton* The mercerizing process (named after its inventor who introduced it to the cotton trade in 1813) consists essentially in immersing the thread in warm 21 per cent hydrogen peroxide for 1 hour This produces a quick shrink and a glossy sheen Mercerized thread is usually 3 ply but is somewhat

stronger size for size than plain thread It shrinks on heating and must, therefore be wound loosely before sterilization As in silk, resistant spores may be present in the interstices of the spun strand, and a single boiling cannot be regarded as an efficient means of sterilization. Autoclaving at 250° F for 30 minutes or 260° F for 5 minutes sterilizes without damaging the thread or materially reducing its tensile strength

SLes

Cotton is usually purchased as ordinary sewing thread in reels or spools and the system of denoting sizes is that of the cotton trade No 40 is the size most commonly used it has a diameter of about 0 4 millimetre approximately that of 2/0 catgut and has about the same tensile strength The approximate corre spondence between cotton and catgut sizes is given in Table II

Tensile strength

The tensile strength of cotton is rather less than that of silk or linen thread of the same diameter there is however a marked variation in different samples and no generally applicable table is available.

Linen thread

Linen thread is not now often used in ordinary surgical procedures

Plain linen is the spun fibre of the flax. Pagenstecher thread is linen thread treated with celluloid solution It is more pliable smoother and less " capillary " than untreated thread It is used to a larger extent on the Continent than in Great Britain or the United States of America

Horsehair

This is obtained from horses tails. It is monofilamentous, smooth and non capillary it is brittle and has a tendency to break at the knot It is obtainable only in fine sizes and its tensile strength is low It can be sterilized by boiling. It is still used by some surgeons for suturing skin in delicate areas such as the face and eyelids

FASCIAL AND DURAL SUBSTITUTES

Numerous attempts have been made to find materials suitable for implantation into the tissues to act as a protective layer in the prevention of undesirable adhesions in various sites, notably around tendon sheaths in the peritoneal cavity and over the surface of the brain Most have been discarded as unsatisfactory and need not be discussed here plastic films and metallic foils are dealt with in other chapters. Two natural " substances are finding increasing use particularly in neurosurgery and deserve mention here

Fibrin film

Parallel with the researches which led to the production of fibrin foam as a haemostatic agent (described below) Ingraham and Bailey (1944a) have shown that fibrinogen and thrombin allowed to clot under certain controlled conditions, produce a film which meets the requirements for a dural substitute The film has been prepared in sheets tubes and fibres (Ferry and Morrison 1944) Ingraham and Bailey have shown that both in animal experiment and in clinical use these

films are easy to handle evoke little or no tissue reaction cause no irritation phenomena when left in contact with cerebral cortex, and are *superior to fascia lata* or to any extraneous materials

Gelatin film

Just as there has been a tendency for fibrin foam to be replaced as a haemostatic agent by gelatin sponge, so fibrin films for use as *dural substitutes and other* purposes seem to have given place to films of gelatin Gelatin film is now readily available. It is supplied ready sterilized in sheets 4 by 5 inches in size It is slightly thicker than cellophane and is transparent It cuts easily but tends to crack if handled roughly When moistened it becomes much more pliable and if care is exercised to avoid tearing it can be sutured It can be resterilized by dry heat and no special storage is necessary These two properties and its low cost, give it a very definite advantage over fibrin film and make it much more generally applicable McKissock (1952) has reported on its use in 30 cases comparing it with a similar series of 30 cases in which tantalum foil was used as the dural substitute and concluded that the gelatin film implant gave much less trouble than did the tantalum foil. No complications occurred in any of the patients with gelatin substitutes, but 6 of those with tantalum substitutes developed infective complications and 3 had actually to have their bone flaps removed The effectiveness of the gelatin and tantalum in preventing post-operative epilepsy appeared to be about the same. The original articles should be consulted by those interested in the use of these new materials.

ABSORBABLE HAEMOSTATIC AGENTS

These are a new class of materials fairly recently introduced into surgery they are finding an increasing use particularly in neurosurgery and in the surgery of solid organs such as the liver where haemostasis by " orthodox " means may be difficult or impossible.

A number of quite different substances are now available for this purpose.

Fibrin foam

This, the first of the absorbable haemostatic agents, was introduced in 1944 by Ingraham and Bailey (1944b) as part of an extended study of the clinical uses of the various products of fractionation of human plasma. Its use was actually first suggested by Gray in 1915 It is prepared in a thrombin free form, and is a " foamy " solid comprising dense strands of fibrin fibres between which are air spaces of both macroscopic and microscopic size In the dry state it is firm and rather brittle, but on being moistened with saline, thrombin solution, or tissue fluids it becomes rubbery and can be moulded into suitable shape. It is easier to handle than muscle fragments, which have usually been the neurosurgeon's standby for haemostasis and for large oozing surfaces a thin wafer of foam can be cut to the desired shape and pressed on the whole surface, after moistening in the thrombin solution which is supplied with the foam.

Gelatin sponge

This substance was introduced by Correll and Wise (1945) and has found its greatest use in neurosurgical operations. It is a water insoluble gelatin-base

sponge, which is supplied in small blocks which can be cut into pledgets or swabs, or into specific shapes for filling cavities. Its properties and the reaction of the tissues to its implantation were carefully investigated by Pilcher and Meacham (1945) who showed that it was quite devoid of toxic or antigenic properties, and that even pieces of considerable size were completely absorbed within 30 days, compared with up to 100 days for an implant of fibrin foam of the same size. Tissue reaction was phagocytic rather than fibroblastic.

Used by itself it has some mechanical action in promoting coagulation, but it is usually used in conjunction with thrombin. A freshly prepared thrombin solution is used to moisten the sponge before it is applied to the bleeding area. Haemostasis is usually rapid and effective. Jenkins and his colleagues (1946) have shown experimentally that patches of gelatin sponge will arrest haemorrhages from wounds in the vena cava and even in the ventricle. It has been shown, too, that haemostasis can be effective even in patients under the influence of full therapeutic doses of anticoagulant (Laufman, Preston and Bourdeau 1952) and in the bleeding diathesis sometimes seen as a complication of radiotherapy (Bourdeau and Laufman, 1953)

Considerable work has also been done on the use of gelatin sponge, usually in powdered form, in control of acute gastro-intestinal haemorrhage McClure (1952) gives a number of experiences of its use in this connexion.

Biopsy diagnosis of carcinoma

In another direction altogether gelatin sponge has been used apart from its haemostatic properties, as an aid in the biopsy diagnosis of carcinoma. Gladstone (1948) has described a technique whereby a small piece of gelatin sponge on a forceps is wiped over an ulcerated area of the cervix uteri. Fluid, cells and tissue particles are absorbed by the sponge, which is then fixed in formalin embedded and cut in exactly the same way as a block of tissue It has the advantage over the Papanicolaou technique that exfoliation of cells is not essential, and the admixture of extraneous cells from the vagina is avoided Gladstone has suggested the extension of the method to carcinomas of mucous surfaces both in bowel and mouth.

Oxidized cellulose

This is not strictly a natural substance, but is so widely used that it should, perhaps, be included here. It is readily obtainable relatively cheap and in the opinion of many surgeons is the absorbable haemostatic agent of choice, especially in surgery of the liver It is supplied as small rolls of gauze, which can be handled exactly as a gauze swab, but which may confidently be left *in situ* in the peritoneal cavity or elsewhere without fear of untoward results.

The properties of oxidized cellulose were fully described by Frantz and Lattes (1945) The material is prepared from cotton gauze by oxidation with nitrogen dioxide with the formation of cellulosic acids. It can be sterilized by formalin, and is put out by the makers in small ready sterilized swabs. It can be used dry requires no admixture with thrombin or other coagulant, and can be safely used in most sites. Frantz and Lattes showed, however that it does appear to have an inhibiting effect on bone formation and therefore in bone surgery it is generally less acceptable than gelatin or fibrin. Stinchfield (1950) has made the suggestion

that this property might deliberately be taken advantage of in arthroplasty where bone formation has to be kept at a minimum.

Starch sponge

The above three haemostatic agents are all relatively expensive Bice Mc Masters and Hilbert (1944) have described the preparation of a starch sponge It is prepared by slowly freezing a starch paste, squeezing to remove water and then drying under vacuum or in a drying oven Rosenfeld (1945) has shown that it is effective in stopping both capillary oozing and bleeding from the large veins and that it can be left in the tissue without producing any undue tissue reaction Ritter and Bloomberg (1952) have shown that starch sponge implanted into the prostatic cavity after prostatectomy is effective in stopping bleeding, and is eliminated from the cavity by absorption and solution in the urine within 4 hours This substance is marketed in the United States of America as Solusponge, but does not appear to be available at present in Great Britain Since it can be produced so cheaply it appears to be worthy of further investigation

Alginates

While all the haemostatic agents so far described have been developed in the United States of America, there is another substance whose uses have been investigated primarily in Great Britain This is calcium alginate obtained from a number of seaweeds growing naturally off the Scottish and Irish coasts The parent substance is alginic acid, a polymer of mannuronic acid with an empirical formula of $C_6H_{10}O_7$. Its sodium salts are water soluble, with marked hydrophilic colloidal properties, while the calcium salts form an insoluble precipitate. By varying the preparation of calcium and sodium salts present, products with varying rates of action and absorption can be produced.

For haemostasis the alginates are used in the form of wool or gauze and gauze of different rates of absorption can be obtained for specific purposes Unlike oxycellulose (which is also a polyuronic acid) alginates do not appear to retard bone repair nor to interfere with penicillin or thrombin activity Furthermore they can be readily sterilized either by autoclaving or by dry heat. Just how the alginate gauze acts to promote haemostasis, except by the mechanical haemostatic action possessed by any material which, by its physical structure as a wool, foam or gauze, provides a greatly increased clotting surface, is not clear Its effectiveness, however has been repeatedly demonstrated, and Blaine (1951) in a comparative study of absorbable haemostatic agents showed that it was in no way inferior to gelatin sponge in haemostatic effect.

GLOVE POWDERS

The importance of finding a substance for use as glove powder which is at once effective, capable of easy sterilization not injurious to gloves, and innocuous when accidentally (as may easily happen) implanted into the tissues, particularly the peritoneum, has been increasingly recognized in recent years. Until recently the standard basic ingredient of all glove powders has been talc.

Talc

Pure talc is a hydrous silicate of magnesium : commercial talcum powder is a mixture of talc, serpentine and dolomite It was introduced for use as a glove powder when the dangers of lycopodium and other organic substances became apparent, and has for many years been regarded as the ideal substance. Antopol (1953) in a paper chiefly devoted to the noxious effects of lycopodium powder described the first talc granuloma, and since then numerous examples have been published. The subject will not be reviewed in detail here Granulomas may be formed in almost any tissue, but it is in the peritoneum that the noxious properties of talc are most evident intestinal and peritoneal adhesions, with their inevitable obstruction complications can result from implantation of quite small quantities of talc and as the finger of a carelessly applied and over powdered glove may contain as much as 100 milligrams of talc, the risks of its use are considerable Seelig, Verde and Kidd (1943) gave an interesting historical account of this subject, and there have been numerous case reports published in the last 10 years There is undoubtedly sufficient evidence now to condemn the use of talc in glove powders, and all surgeons should be aware of the dangers associated with its use.

Talc substitutes

Numerous substances have been investigated in the search for an ideal glove powder Most materials which are physiologically and surgically safe have a marked tendency to agglutinate or gelatinize on sterilization and so become useless for their purpose Potassium bitartrate was suggested by Seeling, Verde and Kidd and appears to be safe if carefully sterilized. It does, however un doubtedly shorten the life of rubber gloves and it is hard on the hands.

Modified starches

Starch powder in some form would appear to be the ideal material for the purpose, but all early attempts to use it foundered on the difficulty of sterilizing without agglutination However recently a number of modified starches have been put on the market the exact processes of manufacture have not been revealed by the makers except in the case of Autosorb (Abril) which is a formalin-treated starch Two other preparations are available, K285 (Boots) and Biosorb (Ethicon) which are described by their makers as " starch treated by physical and chemical means to ensure that the powder will not gel on exposure to moisture or steam sterilization " Graham and Jenkins (1952) have experimented with these three powders and have shown that they are all equal to talc in lubricity and in ease of sterilizing and all much less liable than talc to stimulate tissue reaction

There can be no doubt that one of the powders described here should be universally used now in preference to talc. Even with these powders the precaution, so often neglected, of thoroughly rinsing gloves after putting them on and before commencing operating should be carefully observed (Lee, Collins and Largen, 1952)

FIBRINOGEN COAGULUM

A further " natural " substance which may have a practical application in surgery is fibrinogen produced in the fractionation of human or bovine plasma

Dees and Fox (1943) suggested the use of fibrin coagulum as a method for entrapping and collecting small multiple calculi from the renal pelvis. However human fibrinogen has been difficult to obtain is exorbitantly expensive and the method in this form has not come into general use

Moore and Sweetser (1952) however have shown that bovine fibrinogen can be safely used with equal effectiveness. They use a 9 per cent solution of bovine fibrinogen mixed just before introduction with 1 000 units of thrombin injected simultaneously with a special syringe This is introduced into the renal pelvis. Within 5 minutes it forms a firm clot which is then removed with the entanged stones, through a wide pyelotomy Any clot that may be left in the pelvis willl be dissolved by the urine within 12 hours. The original article should be studied by those interested in this technique.

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CHAPTER 17

ANAESTHESIA

JOHN IVES

INTRODUCTION

HUMPHRY DAVY's "pretty green bag" of almost impermeable silk—which fascinated and terrified the young ladies of Clifton in 1799—was not used clinically. Nevertheless, it was this and his famous "Researches" which led directly to nitrous oxide anaesthesia (Cartwright, 1952) and the materials from which the first anaesthetic gas machine was made are still employed today. Barth and Coxeter produced in 1868 a machine of brass and wrought iron cylinders with rubber face piece and rebreathing bag (Duncum, 1947). What is perhaps even more surprising is that sound physiological principles were incorporated into that early machine for instance "The breathing tube ought to be so capacious as to offer no impediment to the most rapid inspiration and to meet this requirement it must be wider than the trachea, to compensate for the resistance arising from friction of the air against the interior of the tube." That was written in 1847 the writer was the incomparable John Snow.

The basic materials may have remained but from them modern industry has brought vastly different products. The mutually stimulating efforts of surgeon and anaesthetist have produced a bewildering variety of tools for use today.

IRON AND STEEL

Cylinders

Barth's early cylinders which weighed 15 or 16 pounds, were heavy and bulky they contained fifteen gallons of gas compressed by force pumps" (Duncum, 1947) and were inclined to blow off their welded ends. Today steel alloys are used for these cylinders the British Oxygen Company's "Flyweight" made of steel, nickel chromium and molybdenum when filled with 100 gallons of nitrous oxide (compressed to a liquid state) weighs only 4½ pounds. Despite its light weight, this cylinder must, before it leaves the manufacturer's hands, be shown capable of withstanding a pressure of 3 000 pounds per square inch and failure of cylinders is unknown.

These "Flyweights are replacing the heavyweight cylinders in portable machines, which usually carry two oxygen and two nitrous oxide cylinders and by this replacement, reduce the dead weight by 20 pounds. Any anaesthetist who has climbed stairs with his "portable" will appreciate this and it is conceivable that Everest could never have been conquered without lightweight cylinders.

Pin index system

The linkage between cylinders and machine has in the past caused disasters. Many attempts to prevent wrong cylinder coupling have been made, for example

the International Cylinder Colour Code, coloured piping, and non interchangeable valves, *but none was completely foolproof* Recently an idea has been borrowed from the radio valve makers—just as Magill in 1932 borrowed the Rotameter from industry and so revolutionized the measurement of gas flow in our machines—and the "Pin Index System" which has been in use in America since 1952, has been approved by the British Standards Institution with the hope that it will be *adopted internationally*

In this Pin Index System each of the cylinder valves is fitted with holes and each yoke has pins. These holes and pins are so placed that it is impossible to connect any gas with any flowmeter except its own the bogey of the "wrong cylinder should have been laid for ever (Fig. 73)

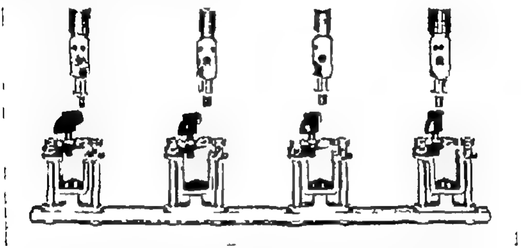


FIG. 73—New non-interchangeable valve system for medical gas administration. An assembly of four valves and matching yokes as they will be when the new pin-index system of non-interchangeable valves is introduced into Great Britain. Two pins on the yoke and corresponding holes in the valve—in different positions for different gases—will make it impossible to connect accidentally a cylinder of gas to the wrong place in the administering apparatus. (*By courtesy of the Editor of Anaesthesia*)

The change over to this system in Great Britain began in the autumn of 1956 Existing machines can be fitted with an adaptor to take the coupling new machines will all have the system Fig. 74 shows one of these machines. Other interesting points are that copper tubing is used to connect yokes to flowmeters that the regulators are directed downwards (a safety precaution suggested by Langton Hewer some 20 years ago), and that two ingenious devices have been used to prevent trichlorethylene making contact with sodalime

Anaesthetic machines

Steel tubing and plate make a satisfactory structure for the majority of anaesthetic machines, but the final finish often leaves much to be desired. The painting and chroming is attractive enough in the showrooms in the average operating theatre these machines are hard worked and all too frequently become chipped and flaked Razor-sharp flakes of chromium plating can inflict quite nasty injuries to fingers and hands perhaps the tougher plastic enamels which are now being tried may provide an answer

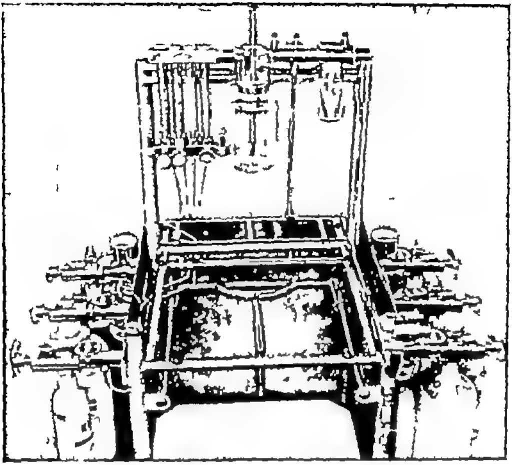


FIG 74.—Pin index machine. *(By courtesy of Medical and Industrial Equipment Ltd.)*

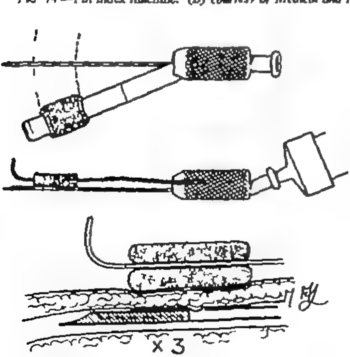


FIG 75.—Mitchell's self sealing intravenous needle. *(By courtesy of the Editor of Anaesthesia.)*

Other anaesthetic apparatus

Stainless steel appears only to a limited extent in anaesthetic apparatus owing to the difficulties of fabrication It is used to make Magill's laryngoscope and bronchoscopes and also for the body of an ingenious thermo-controlled inhaler for Trilene analgesia—the "Airlene" (Airmed Ltd)

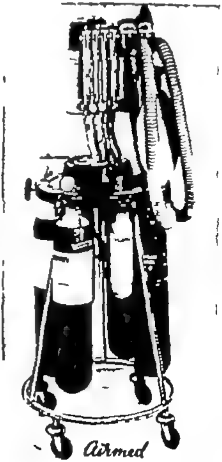
Intravenous needles

"The anaesthetist now demands an ever-open vein" (Macintosh, 1955) and Mitchell's stainless steel needle (Fig 75) satisfies this need Its advantage over its predecessors is that it can be kept free of blood (and therefore of clot) by pressure of the rubber pad, carried on a phosphor bronze spring, against its lateral opening.

ALUMINIUM ALLOYS

These alloys, particularly when hardened by the addition of silicone, are being used increasingly in anaesthetic apparatus. Their lightness, strength and comparative freedom from corrosion are definite advantages, against which must be set greater difficulties in fabrication They are awkward metals to weld satisfactorily and almost always sand castings must be made

FIG 76.—The Marrett transportable outfit. (*By courtesy of Airmed Ltd*)



Marrett transportable outfit

The Marrett Transportable Outfit (Armed Ltd. Fig. 76) which claims to be the lightest and most compact hospital anaesthetic machine yet produced, is a good example of the use of these alloys. Although the traditional metals, brass and copper are employed in the Marrett head the cover is an aluminium alloy spinning, the frame a casting, the covering case is sheet aluminium covered with a

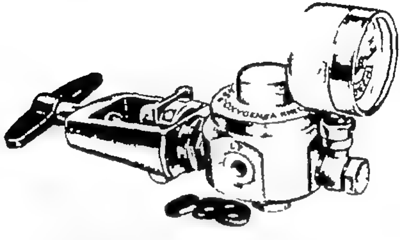


FIG 77.—A new regulator for medical gases fitted with a pin index non-interchangeable yoke and pressure gauge. (*By courtesy of Airmed Ltd.*)

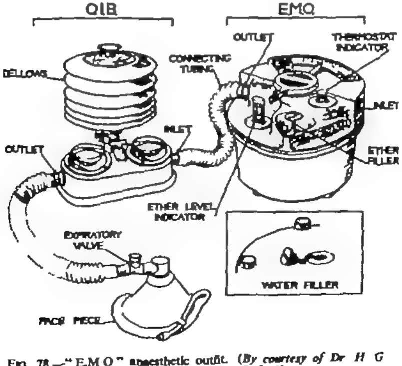


FIG. 78.—"E.M.O." anaesthetic outfit. (*By courtesy of Dr H G Epstein, Radcliffe Infirmary Oxford.*)

plastic process, and the cylinder stand is of aluminium alloy rod argon arc welded Perhaps the most interesting items on the machine are the new lightweight regulators These too are made of aluminium alloy weigh only 8 ounces, and have a beryllium copper diaphragm with stainless steel springs—no rubber is used in their construction (Fig. 77).

The E.M O

Another anaesthetic outfit in which much use is made of castings of these alloys is the "E.M O" (Pentland Instrument Co Ltd. Oxford Fig. 78) This, like the Oxford Vaporizer which it succeeds, does not depend on cylinders It consists of two units an automatic temperature controlled vaporizer which will deliver ether vapour in concentrations varied between 0 and 20 volumes per cent and the Oxford Inflating Bellows This latter unit (Fig. 79) which can be supplied separately has another important field of usefulness as a simple apparatus for efficient artificial respiration It may well become a standard part of the equipment of any ambulance service that is likely to meet with cases needing resuscitation.

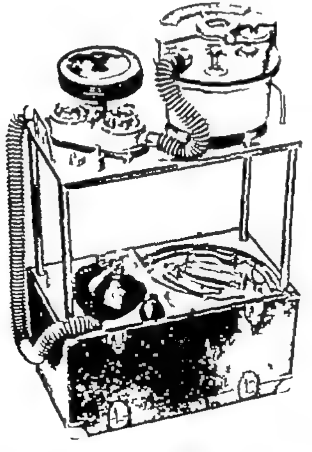


FIG. 79 —Oxford Inflating Bellows. (*By courtesy of Dr H G Epstein Radcliffe Infirmary Oxford.*

Connexions

Connexions and angle pieces, when made of hard anodized alloy are altogether more satisfactory than their chromium-plated brass counterparts. The latter being of soft metal, are too easily damaged and distorted Since there may be as many as twelve jointing surfaces in quite an ordinary gas apparatus, it is important that these fittings should retain their shape

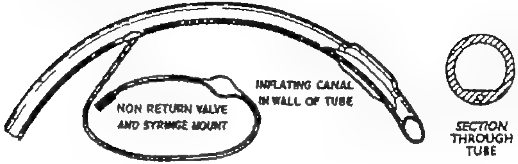


FIG. 80.—" Streamline " endotracheal cuffed tube (*By courtesy of British Oxygen Gases Ltd.*)

RUBBER

It is probable that no gas anaesthetic machine has ever been made in which rubber did not play an important part. For anaesthetic apparatus today the manufacturers have produced a substance which is almost—but not quite—perfect. The various airways and facepieces, with rebreathing bag and concertina tubing —all of rubber—are standard equipment of every machine, yet yearly each of these items is being steadily modified and improved As an example, Fig. 80 shows that British Oxygen Company's " Streamline " endotracheal cuffed tube in which a canal for inflating the flush-fitting seamless cuff is built into the wall of the tube. Because of its smooth surface, it can be used for nasal intubation another improvement is that each tube is supplied with a non return valve for the cuff which fits a standard Record " syringe. Fig. 81 is of a bronchus tube and bronchus blocker recently introduced by the Nuffield Department of Anaesthetics, Oxford, which it is claimed, can be used without a bronchoscope " since it is tailor made its shape conforms closely to the course of the trachea and left main bronchus " (Macintosh and Leatherdale, 1955) Two cuffs are used, an endobronchial one and an endotracheal and there is also a small tube alongside through which the blocked-off lung may be either aspirated or inflated

Static electricity

The one disadvantage of rubber for anaesthetic purposes, is that it is a non-conductor Therefore static charges may develop which can be highly dangerous when an explosive anaesthetic mixture is in use. Before the introduction of the closed circuit technique and the improved heating and ventilation of our theatres, it was considered that the natural humidity of the atmosphere in Britain was sufficient to dispel any danger from static sparks It is now realized that " static electricity is the largest single agent of ignition in anaesthetic explosions " (Ministry pamphlet R.H B (53/55)

An attempt has been made to overcome this difficulty by incorporating a conductor in the rubber during manufacture. "Antistatic rubber" has finely divided carbon (for example that produced by burning acetylene) impregnated to form a loose reticulation of carbon molecules in the non-conducting base On manufacture each item made must conform to an accepted standard of electrical conductivity

Rubber s chief virtues flexibility and elasticity are reduced by the impregnation of carbon This was markedly so in the first specimens produced but by improve-

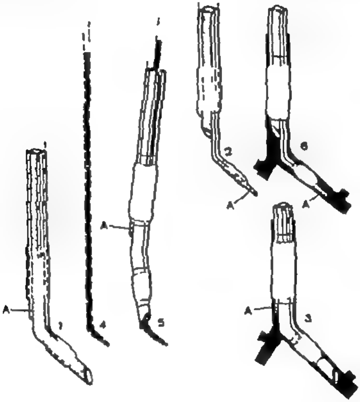


FIG. 81 —Bronchus tube and bronchus blocker
(*By courtesy of John Sherratt and Son*)

ments in processing particularly and partly by a reduction in the proportion of carbon used, the antistatic rubber recently in supply is much better in these respects

It is now almost impossible to distinguish blindfold and by touch alone, between rebreathing bags made of treated and untreated rubber This does not apply to head harnesses but these too are considerably more elastic than those first produced.

However the problem cannot be regarded as having been solved. Rubber stretches and the carbon reticulation does not. Therefore breaks in the reticulation occur with clumping of the molecules and diminution of electrical conductivity To guard against this danger the Ministry pamphlet previously quoted recommends electrical testing at intervals of not less than every 3 months and the discarding of any item of antistatic rubber equipment whose electrical resistance has become outside the range prescribed. Although these tests are said to be "simple

and well within the capacity of a journeyman electrician " it would be interesting to know to what extent these recommendations are carried out.

A recent Report from the Ministry of Health (1956) sums up this matter in these words

> Though the problem referred to us is a very real one we do not wish to exaggerate its importance and for this reason we have sought to be moderate in our recommendations. We appreciate that hospital authorities would rightly hesitate to adopt measures which conflicted with clinical requirements, or even clinical convenience, or which involved heavy expenditure. Nevertheless it is important that there should be a more general awareness of this danger and a realization that since 1947 three patients have died and a number of people have sustained injuries as a result of anaesthetic explosions. There are thus no grounds for complacency

Another section of this Report states

> One of the chief difficulties to be overcome is the lack of any consciousness of danger If every hospital would take simple precautions of the type already observed as a routine wherever any thought has been given to this matter three-quarters of the problem of anaesthetic explosions would disappear

Halothane

The explosion hazard has been tackled in another way by chemical research workers investigating the fluorinated hydrocarbon compounds The most useful of these halothane has been marketed by Imperial Chemical Industries under the trade name of Fluothane. It is a powerful inhalational anaesthetic with many advantages, of which the most important is that it is neither inflammable nor explosive

As always, there are disadvantages. Halothane is a relatively stable compound but, in the presence of bright light and water vapour some decomposition can take place. This is minimized by the addition of a small quantity of thymol and by storing in dark amber bottles. Nevertheless, the decomposition products are liable to attack tin, aluminium, rubber and cork (Bryce-Smith and O Brien 1956)

This sounds a formidable drawback but, in practice, adverse effects on anaesthetic apparatus have been reported only when halothane has been used with closed circuit absorbers Recently a special sealing washer which is impervious to halothane, has been produced (Imperial Chemical Industries) so that a considerable part of this limited trouble can now be avoided.

Langton Hewer mattress

It is part of the duty of every anaesthetist to give thought to the prevention of post-operative morbidity of any kind. Langton Hewer s Antistatic Sponge Rubber Operating Table Mattress (Langton Hewer 1953) is an illustration of this way of thinking. In the past, many complications, for example, brachial plexus palsies, thrombosis of leg veins, have followed the use of apparatus connected with the Trendelenburg position With the Langton Hewer mattress the patient is held in position by skin friction on the corrugations of the mattress no shoulder rests, or any fixing of pelvis or ankles, are required By this simple method, the incidence of these alarming sequelae can be reduced

PLASTICS

In industry the fact that all plastic compounds are insulators is regarded as an important advantage, but it is this same property which has restricted their adop-

tion in anaesthesia There are, of course occasions when the static hazard is not important and plastic materials may be safely used Airways and endotracheal tubes may serve as an example with these both surfaces are normally covered with a film of water vapour which is quite sufficient to dispel any charge The twin channel airway (Fig 82) made from a moulding of polyvinyl chloride is slightly flexible, easy to clean and can be supplied at about one quarter the cost of its rubber counterpart Magill s endotracheal tubes have been produced in a similar material but have never become very popular in Great Britain Although their liability to kinking is no greater than that of similar rubber tubes, the mechanism of kinking is different—with rubber a kink is sudden and produces dramatic obstruction with plastic, it is gradual and a less easily noticed obstruction may develop These plastic tubes have one compensating advantage—they are reported to show none of the rapid deterioration that occurs with rubber used in tropical con ditions.

Non irritating polythene tubing is used where intravenous therapy has to be long continued and also in continuous caudal analgesia and extra dural lumbar block. Another

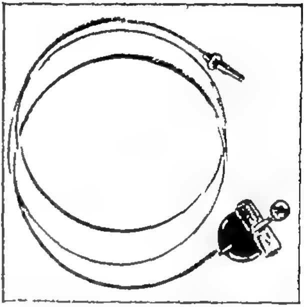


FIG 83—Intravenous unit for remote control. Unit comprises Gordh needle, 6 feet fine plastic tubing and Record fitting needle mount. (*By courtesy of Medical and Industrial Equipment Ltd*)

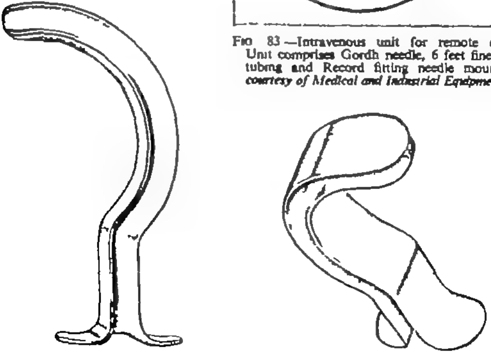


FIG 82.—The M I.E. twin channel plastic airway (*By courtesy of Medical and Industrial Equipment Ltd*)

ingenious use for this tubing is for the remote control of an intravenous unit (Fig. 83)

Oxygen therapy

For oxygen therapy facepieces and rebreathing bags, if made of plastics, can be as little as one-sixth of the weight of the ordinary rubber B L.B mask and this adds greatly to the patient's comfort. Another advantage is that the facepiece can be translucent, which makes it easier for the nurse to observe her patient's colour These features are incorporated in the Airmed Oro-nasal Oxygen Inhaler It is connected to the supply cylinder or pipe line with unkinkable plastic tubing and the flowmeter for this apparatus is also of solid translucent plastic.

Electrical resistance

No process has yet been discovered by which the electrical resistance of plastics can be sufficiently lowered for use with explodable gases Static charges are a considerable nuisance in various industrial undertakings such as gramophone record making, duplicating, photography and here much research has gone into lessening the evil A number of substances have been produced which, by their surface application, or by incorporating them into the inert fillers that are used in the manufacture of plastic and synthetic rubber materials, can diminish the accumulation of static charge sufficiently to prevent dust pick up and adherence of materials to one another Examples of these compounds are " Antistatic Plasticizer " (Bayers, Germany) which is a polyglycol ether and Cationic S P " (American Cyanamid Co) an emulsifying agent of the quaternary ammonium type

It appears, however that the addition of these compounds in sufficient concentration to satisfy electrical standards in anaesthesia is likely to make the finished article brittle. This destroys one of the principle attractions of these materials. Perhaps this difficulty will be overcome if solid nylon could be made antistatic, it could become a most useful material for the making of anaesthetic implements.

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CHAPTER 18

RAW MATERIALS USED IN THE CONSTRUCTION OF ARTIFICIAL LIMBS

LEON GILLIS

NATURE WORKS in such a way that with the least possible quantity of material the greatest strength is attained The bones of animals and of man are hollow cylinders In birds, where it is especially important for the weight to be minimal and where great strength is required the thin substance of the bone is remarkable Engineers have availed themselves of this principle and iron columns, destined to support great weights, are cast hollow On the same principle iron beams are made deep in the direction in which they sustain the pressure and narrow in the direction at right angles to this and they are not infrequently pierced about their neutral surface.

It is clear that to construct a mass capable of sustaining transverse strain equally in all directions it must be shaped as a cylinder It is, therefore natural for an artificial limb to be cylindrical in order to achieve strength lightness acceptable cosmetic appearance and functional utility

At present artificial limbs are constructed from a multiplicity of materials both naturally occurring and synthetic.

In selection of suitable materials the following criteria should be satisfied

Functional considerations	1 They should be sufficiently strong and not be subject to work fatigue 2 At the same time they should not be too heavy or cumbersome to interfere with function
Compatibility	3 The material should not have any injurious effect on the wearer 4 The natural secretions of the body must not cause any undue deterioration of the prosthesis

CONDITIONS GOVERNING SELECTION OF MATERIALS FOR LIMB-MAKING

Medical considerations

Among the many qualities looked for the material must be known to be chemically inert, non-adhesive, non hygroscopic hygienic and non-abrasive

Considerations in manufacture

Among the properties to be considered from the manufacturing point of view is that the substance is easily fabricated By this it is meant that the material can be easily cut drilled riveted, machined or readily jointed by adhesives It must be capable of easy moulding, working or curing and readily adjustable after manufacture The material must also be of low density

Wood

This material is commonly used in the manufacture of sockets of artificial limbs and in making artificial feet. It is frequently used to make complete limbs, particularly the lower extremities The chief disadvantage is that it is subject to cracking and splitting.

Willow

Willow is the most suitable wood available, though ash and larch can also be used Lightness is of great importance especially when used for artificial feet. Willow is also most suitable for use in tropical countries, as it is immune from attacks of white ants

For the purpose of manufacturing artificial limbs, willow is obtained chiefly from the eastern counties of England, where it grows in marshy soil Wood of the required size is produced in from 12 to 20 years. The most suitable trees are those from 12 to 17 years old having a girth 4 feet (1 2 metres) from the ground of not less than about 46 inches (1 metre) Coppice-grown trees, owing to close planting, have tall, straight trunks with few long branches This is a great advantage from the point of view of economy and utility

The trees are selected before being felled, the species for choice being *Salix caerulea* the same variety as is used for cricket bats. After felling and logging into suitable lengths, the willow is seasoned in a drying shed exposed to the air but not the wet for periods of 3 to 5 years In times of emergency when large quantities may be needed quickly more rapid methods of seasoning, such as kiln-drying, are applied but are not popular with the limb-makers. The naturally seasoned wood proves more satisfactory and workable than that seasoned by any other method

Advantages of wood sockets

Wood sockets have an advantage over metal for they can be more easily adjusted and excavated in parts which are liable to give pressure. They also facilitate natural ventilation and are particularly suitable for tropical climates, as willow sockets do not deteriorate from contact with a corrosive perspiration Wooden sockets lack the properties of ductility and malleability possessed by metal sockets, and therefore adjustments to decrease their size are made by adding suitable material inside. Recently experiments in lining willow sockets with a plastic material which takes up stump shrinkage have been carried out with some degree of success.

Leather

There is a wide range of leather available and each kind has its own particular use In the manufacture of artificial limbs ox hide is the type commonly used The advantages claimed from the point of view of socket making, are its adaptability for moulding and its freedom from a tendency to split.

Oak bark tanned shoulder leather is also used for making leather sockets of all kinds. It is supplied in various thicknesses according to special requirements. When soaked in water it can readily be blocked and so can conform to all the shapes and contours which are met with in amputation stumps. Linings are made of horse hide, which easily stretches without soaking and provides a soft surface to

the socket. Soft corsets are made from bridle leather as are also pelvic bands or belts.

Different weights of leather are used and the thickness selected depends upon the part for which it is required For instance heavy sole leather is used in the construction of a thigh socket now rarely seen in Great Britain and light harness or strap leather in the making of a socket for a forearm prosthesis. On account of its flexibility a leather socket can be made adjustable by means of straps and buckles, eyelets and laces, or zip fasteners. This is particularly useful where the distal portions of the stump are larger than the proximal portions as occurs with a disarticulation of the knee or a Syme amputation or where curved surfaces undulate, as with forearm stumps. Leather that has been blocked to shape can be attached to wood or metal by rigid steel plates.

Corsets are made of leather in below knee stumps, but it must be pointed out that leather sockets for above-knee amputations have certain disadvantages which have led to their abandonment in Great Britain These are as follow — *When the socket is drawn in by laces or straps it tends to become circular rather* than triangular in form and loses its accuracy of fit. On the other hand if the leather is made thinner the straps and lacings pull it unevenly in some places causing bulging and swelling of the stump with painful and uncomfortable sequelae. A prosthesis with a leather socket is heavier than one with a wood socket because, to make it rigid, the leather must be thick. The leather also requires metal parts to connect it with the shin piece or any other part of the appliance. Further leather tends to smell from absorption of perspiration and it is hot to wear

Light metals

The advent of aluminium alloys has influenced the design and manufacture in many components of artificial limbs, for with modern metallurgical techniques they are more easily supplied to standard specifications than is possible with natural materials such as wood and leather

There is a wide range of alloys available in the form of sheet, or forging material with accurately known properties which are selected according to the requirements of the particular component. Many items such as shin pieces, knees, arms and wrist parts, are produced in quantities by a manufacturing technique that ensures components of known physical properties, as, for example, ductility and malleability It should be borne in mind that most components of an artificial leg—shins sockets, and so on—are made to bespoke measurements and mechanical production can proceed only to a certain point, after which the component has to be modified by stretching or shrinking by hand to suit the dimensions of a particular patient.

Corrosion caused by body secretions has been the subject of much research and a strong light alloy sheet material covered with a very thin layer of pure aluminium has been evolved to prevent such corrosion This light alloy is known as Alclad, and experience has shown that whilst the properties of duralumin have been retained the coating of pure aluminium has produced great resistance to corrosion caused by body perspiration It should be mentioned that aluminium itself has not been found suitable despite its acid resisting properties because its strength in relation to its weight does not compare with its alloys.

Steel

Steel is universally used for particular parts of artificial limbs in view of its high tensile strength and the fact that it can be hardened for ball-races. The normal type used in the industry is 3 per cent nickel case-hardened steel which has proved to be most satisfactory

Joints of the hip knee and ankle are machined from steel forgings, and in some cases, such as Syme appliances stainless steel of the highest quality is used for the anterior and lateral supports. It has also been found that in certain components, such as the free-wheel knee control, steel must be used for certain parts, despite the increase in weight, because dural castings will not stand up to the frictional wear

Plastics

There are two main types of plastic produce today namely

1 *Thermoplastic* resins which are capable of being moulded to the shape of a cast or last by heat and their shape changed to suit the amputee s specific require ments at trial or delivery but, unfortunately this group is neither sufficiently rigid, strong, nor safe enough for prostheses.

2. *Thermosetting* resins which are generally laminates of resins bonded together with either textile or nylon cloths. Again a cast or last is required and a moder ately simple process is necessary to form the component, which when correctly polymerized, is strong, rigid and corrosion resistant. They are however incapable of modification by heat after bonding, and the only way to change their shape to suit the specific requirements of the amputee is by cutting or machining in some way

In Germany the epoxy resins are used with fibre-glass and cotton and nylon stockinet in a laminating technique whilst in the United States of America polyester resins are combined with fibre-glass and cotton stockinet. A Norwegian above knee artificial limb with a suction socket has been shown made from a thermoplastic resin (Plexidur) the knee and ankle mechanisms with the exception of the axle in the knee being made of a phenol formaldehyde and fabric laminate. One outstanding advantage of these synthetic materials for artificial limbs is that their manufacture does not entail the costly apparatus and specialized skill that metal does another is that they do not corrode.

Both on the Continent and in the United States of America components of limbs or complete limbs have been made of plastic material either of the thermo-plastic or thermosetting type but it is considered in Great Britain that neither accurate fitting nor a reasonably designed leg can be obtained from the present range of materials In Great Britain glass laminate components such as shins, have been developed for artificial legs and after long field tests have been found to meet the conditions mentioned above and with respect to sockets polyethylene is regularly used with suitable reinforcement for selected cases.

In Great Britain plastics have not as yet been used to any great extent in the manufacture of artificial limbs. Experiments are being carried out with a view to determining whether or not, with constructive and careful application, the advantages which these materials offer can be utilized Several types offer tre-mendous possibilities. One technique in particular that of low pressure lamination on which a considerable amount of experimental work has already been done, would appear to be the most practicable from the point of view of strength with

light weight simplicity of mould design and low initial cost of tooling compared with that of metal limbs Various materials which are eminently suited to this technique are available First the one which has shown most promise is an asbestos felt material impregnated with a phenolic resin The trade name is Durestos The felt is roughly tailored and built up in layers on a form or mould to the required thickness It is then cured in an oven at a predetermined temperature for a period which varies according to the particular thickness required or type of mould used After curing the moulding is withdrawn from the mould trimmed and coated with a cellulose paint This material can be worked with normal metal tools riveted and with certain restrictions treated as sheet metal. After Durestos has been cured it cannot be altered this rules it out for general use, except as a temporary prosthesis

Another material is Nuron a polyester resin Laminated materials made by using this resin as a bonding agent for woven glass fibres have remarkable strength while being very light in weight. In this case the glass cloth is either dipped or painted with resin which has been made up to a given formula and laid on in layers round the mould or former which can be either metal or plaster The whole is then encased in a cellophane bag which is deflated causing the air which tends to inhibit the curing of the resin to be evacuated from the layers In this state it is then subjected to ultra violet light or heated in an oven which process cures the resin Credit is due to Imperial Chemical Industries Plastics Division for the initial development of this technique.

After-care maintenance such as repairs and so on may well prove simpler while with the use of certain thermoplastic materials adjustments in the actual socket of the limb to accommodate bony prominences temporary skin break downs and so on could possibly be made on the spot with ease Experiments have already proved that this is feasible The ideal plastic has yet to be evolved, but those responsible for the design of prostheses are in constant touch with the plastic manufacturing industry so that new materials can be tried out.

Bespoke manufacture of prostheses limits the technique to be employed in the use of materials. Plastics that conform as nearly as possible to the characteristics of duralumin sheet in strength density durability machinability and heat treatment would be satisfactory particularly if medical conditions were also fully satisfied

Cosmetic hands

Plastic gloves are now manufactured to restore mutilated hands to such a realistic appearance that they defy anything but the closest scrutiny After many years of research and experiment, a cosmetic hand has been produced which gives an almost exact natural, skin-colour reproduction with pigmentation joints knuckles palm areas, veins and even hair to simulate a normal hand Even finger prints can be reproduced in the resins from which the hand is moulded Similar fidelity of appearance has been achieved for legs ears noses and other portions of the face and body The hands may be fitted like a glove over a suitable core or frame or used with various mechanical finger-control devices The material is almost as ageless as natural skin has a warmth that is pleasing to the touch and when soiled may be wiped clean with soap and water

The vinyl resins used in the artificial hand can be moulded at very low pressures

contain pigments or fillers but no volatile solvents and have a high viscosity flow comparable to heavy oil.

The mould is made by taking an impression of a hand similar to that of the patient, and afterwards forming a cast of dental plaster from the impression This male core serves as a master from which a two-piece sprayed metal mould is made. After the mould has been made rigid vinyl finger nails are fixed in place various colours are introduced to reproduce skin tones and a base skin tone is applied. The two halves of the mould are then joined together the resin composition is poured into the mould and heat applied Realism in the finished hand includes hair which may be inserted with a specially designed needle

TYPES OF PLASTICS AND THEIR CHARACTERISTICS

Types	*Characteristics*
Polyvinyl chloride, p.v.c.	Thermoplastic. Chemically inert. Non-hygroscopic. Various forms and thicknesses. Sheet, rod and tubular suitable for shaped supports.
Polythene	Useful where incontinence, perspiration or suppurative conditions are present. Is resilient to local pressure. Adjustments can be made to shape for fitting purposes.
Alkathene	Alkathene is the trade name of a polythene plastic material produced by Imperial Chemical Industries Ltd. It is a thermoplastic, that is, it can be rendered pliable for moulding or fabrication purposes by the application of heat. It is produced in a large number of grades in either liquid or solid form. Its physical properties allow the material to be used for many applications. It is mechanically tough over a wide temperature range. The sheet can be shaped or moulded by heating in boiling water It cuts fairly easily with a knife and can be drilled, tapped for screw threads, riveted or stitched. The sheet form is used for prosthesis designs for cases of incontinence, suppurating sores and so on, where normal leather or textile materials are unsuitable.
Acrylics, such as Perspex	Non-abrasive and non-adhesive. Hygienic.
Phenol formaldehyde resin	Thermosetting. Has a limited use in liquid form for casting fillings in metal parts where hand shaping of wood or other materials would be cumbersome. Phenol is driven off during curing process. Has been used for waterproofing parts of artificial legs, such as feet, which will come in contact with sea-water
Phenol formaldehyde bonded materials	Thermosetting. Are used extensively for sockets of above knee prosthesis such as pylons.
Durestos type	Have proved amenable to working on contours incorporating double curvature such as the ischial seating area. Phenol is driven off during process. When fully cured are very strong, of low density and can undergo usual machine processes as for metal, that is, drilling, riveting, and so on. Chemically inert. Non-hygroscopic.
Plastic finishes	
Phenol resin, phenoglaze type	Cold-setting. Hard and durable. Chemically inert. Non-abrasive and non-adhesive to the skin. Non-hygroscopic, hygienic.
Bonded laminates	
Muslin Certalmid combination	Casein base. Is used extensively because of ease of manipulation. Overflexion of muslin fibres due to excessive local stress tends to induce incipient cracking and break down. A cellulose nitrate finish is applied, but if this is removed by wear body excretions can cause breakdown of material.

CONCLUSION

The careful and conservative attitude of the medical profession towards any change in materials specified by them renders the possible adoption of anything new a long drawn-out procedure and therefore any perceptible trends must have a very wide interpretation

The materials used in the manufacture of prostheses should conform to the standards laid down for other medical or surgical materials in as much as that they have been thoroughly tested are easily recognized and readily obtainable

It would appear that the ideal material must be a combination of the desirable characteristics possessed by a number of indiviual prosthetic materials which at present are used in combination providing soundness of structure and satisfying surgical requirements.

Although there is little plastic material that is available at present the current rapid development in this field suggests that it will eventually replace material derived from natural sources Adhesive bonding of these synthetic substances will replace riveting and other older methods of fabrication

Many efforts have been made abroad (by a complexity of mechanical equivalents) to restore muscle control impaired by amputation The results so far do not appear to be generally acceptable particularly to those believing in simplicity of construction

The introduction of new materials which can be easily fabricated into various types of very light and efficient mechanisms at low cost will undoubtedly accomplish much that is unacceptable at the present time. There is evidence to show that the present trend in mechanical design follows the many parallels arising from research in the aeroplane industry Many patents have been granted for ideas that have their inception in functional movements originally intended for aircraft use.

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CHAPTER 19

MATERIALS FOR SPLINTS

JOHN T SCALES

PLASTER CASTS AND PLASTIC SPLINTS

OVER THE YEARS a multitude of appliances has been devised, utilizing many different materials, which benefit patients to a greater or lesser degree It is not within the compass of this chapter to discuss the merits or otherwise of particular appliances, but rather to describe the methods of manipulation of certain materials which have been found useful for splints. (The trade names and manufacturers of materials are given, as experience has shown that the particular products mentioned have proved satisfactory however other manufacturers products may be equally satisfactory but the author may not have had experience with them.) Splints may be required in the treatment of two broad groups of patients

1 Those who have sustained an injury or are subjected to some operative procedure which necessitates the prompt application of an immobilizing splint, which must perform its function as quickly as possible (for example in the treatment of fractures)

2. Those who are suffering from a condition which may require a splint (*a*) for partial immobilization and limitation of movement (for example synovitis, sciatica) (*b*) to prevent or correct a deformity (for example peripheral nerve injuries, poliomyelitis) (*c*) to assist in the restoration of function (for example after tendon repair or amputation)

The materials to be described are not suitable for such instruments as walking calipers and Thomas's splints as, at present, there is no synthetic material equivalent in mechanical properties to steel aluminium alloy or titanium on a volume for volume basis.

Properties

While there are some minor differences in the properties required for materials used in the treatment of the above main groups of patients the ideal splint material should possess the following characteristics It should

(1) be suitable for direct application to the patient
(2) be easy to mould to the desired form
(3) have a quick setting or hardening time
(4) not contain constituents which may cause dermatitis, be absorbed through the skin, or produce undesirable effects on inhalation
(5) be unaffected by fluids, such as water urine, oils
(6) not require elaborate apparatus for manipulation
(7) be porous to water vapour
(8) be radiolucent
(9) be unaffected by ultraviolet light

(10) be light in weight
(11) have adequate rigidity but be locally deformable
(12) be freely available at a low cost

No one material possesses all these attributes although certain plastic materials come near to the ideal

For the treatment of patients in group (1) plaster of Paris in combination with fabrics is the most satisfactory material to use for what might be called the acute splint because of its ease of manipulation convenience of use, lack of toxicity short setting time and low cost Resin impregnated plaster of Paris is now available which produces a lighter cast with improved properties.

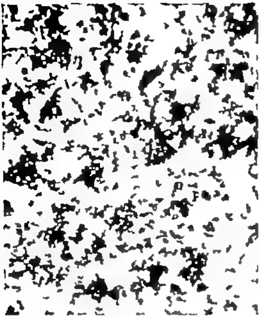
Splints used in the treatment of group (2) patients are often more efficient if plastic materials are used but these chronic appliances usually require to be moulded on positive plaster casts which can be adjusted to allow for bony prominences, scars sinuses, and so on The success or failure of the moulding, however largely depends on the skill of the person taking the negative plaster casts. It is necessary to have a knowledge of plaster of Paris technique to make the negative or positive casts which are required as moulds

PLASTER OF PARIS

Plaster of Paris or calcium sulphate hemihydrate is produced by heating selected washed gypsum to drive off part of the water of crystallization The product is then ground to a fine powder (Fig. 84*a*)

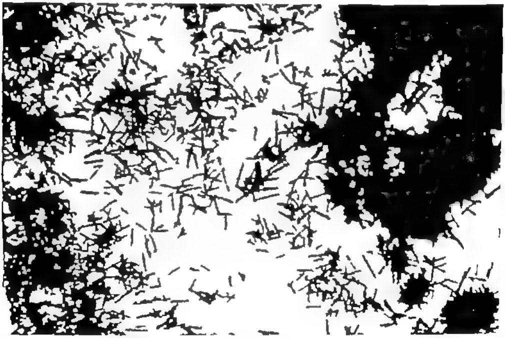
$$CaSO_4\,2H_2O \underset{H_2O}{\overset{Heat}{\longleftrightarrow}} CaSO_4\,\tfrac{1}{2}H_2O + 1\tfrac{1}{2}H_2O$$

When water is added to this powder crystals of gypsum (calcium sulphate dihydrate Fig. 84*b*) are again formed with the evolution of heat. This being a chemical reaction it is possible to accelerate or retard the setting process, and commercial products contain various additives aimed at controlling the rate of setting, expansion and heat production The volume of water added to a given weight of plaster of Paris is critical for greatest strength Water in excess of that required for recrystallization is necessary to give the requisite consistency of the paste for satisfactory manipulation If too much water is added, the strength of the final product will be lowered because of dispersion of the crystals and their failure to interlock adequately Setting or crystallization starts in a few minutes after mixing the water and the plaster and is complete in about 20 to 30 minutes depending on the grade of plaster used Once the process has become established, it is essential that the cast is not interfered with in any way many failures of splints are caused by fiddling with casts during this very critical period when growth and interlocking of the crystals are taking place The rate of setting is influenced by the temperature of the water heat accelerates crystallization The drying of the cast, which partly depends on the humidity of the surrounding air may be accelerated by heat and adequate ventilation excessive heat producing a surface temperature of the cast above 80° C will reduce the final strength



(a)

FIG. 84.—(a) Gotham superfine plaster of Paris. (b) Set Gotham superfine plaster of Paris. (× 150.) (*By courtesy of Smith and Nephew Research Ltd., Hunsdon, Ware England.*)



(b)

NEGATIVE PLASTER CASTS

Materials

Plaster of Paris bandages

These bandages may be either hand made or purchased from commercial suppliers.

The hand-made bandages are produced from strips of sized cotton muslin up to 5 yards in length. The greatest convenient width is 8 inches. The size may be starch, which can be detected by applying a drop of iodine which gives a blue colour in the presence of starch. Some sizes inhibit the setting of the plaster and it is therefore advisable to check with the supplier of the muslin that a suitable size has been used. The construction of the fabric, that is the number of threads per inch in the warp and weft directions, should be between 26 and 38 in the warp and between 24 and 32 in the weft. The strips should be cut from the sheet with picot scissors so as to give a serrated edge which does not unravel. If the strips are torn from the sheet, loose threads often result which can cause constriction bands around the limb or make application of the bandage difficult.

White alabaster, superfine Italian plaster, dental plaster or calcium sulphate dehydrated *B.P.C.* is well rubbed into the mesh of the bandage, which is wound loosely on a ½-inch diameter core (Fig. 85). Hollow or cruciate cores used in commercial bandages may be salvaged and used for hand-made bandages. The completed bandages must be kept in an airtight tin which is sealed with a vapour proof adhesive tape. The tin should be stored in a warm, dry atmosphere.

FIG. 85.—Plaster being rubbed into bandage. The bandage is lying on a layer of plaster about 1 inch deep, contained in a zinc-lined tray.

Commercially manufactured bandages are usually made from a leno construction muslin which is easier to manipulate than normal-sized muslin when wet (Fig. 86). The method of manufacture is to mix the plaster with a binding agent and to apply it as a slurry to the fabric. The binding agent ensures proper retention of the plaster by the fabric. The bandages are wound under the correct tension on cruciform or perforated tubular cores, which ensures that they are evenly wetted out. When wet the plaster is not lost from the bandage to anything like the extent which usually occurs with hand made hospital bandages. Each bandage is

wrapped in a moisture proof package Dry casts have improved mechanical properties compared with those made from hospital bandages

Stockinet

This is a seamless tubular circular knit fabric with considerable elasticity and should be used to protect the skin when taking a cast. Various grades are available but it is false economy to use inferior ones. A satisfactory material * has the following specification Rib stockinet (loom state) 1 × 1 rib knitted on rib machine with ten needles per inch in dial, ten needles per inch in cylinder Yarns two ends of 35s cotton yarn fed as one, 32–34 courses per inch. 35s cotton yarn is 29 400 yards per pound.

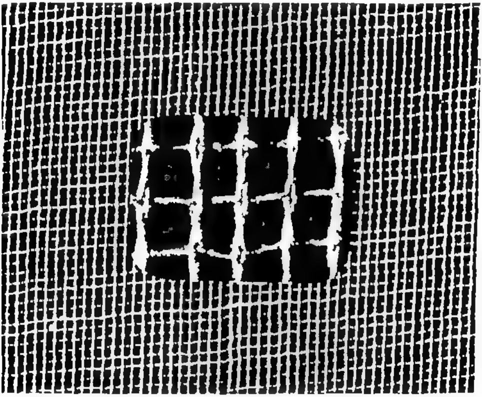


FIG. 86.—Bleached cotton muslin of leno construction. (× 2, × 10) (*By courtesy of Smith and Nephew Research Ltd., Harlow England.*)

Padding

One quarter of an inch thick adhesive backed felt, sponge rubber or foamed polyurethane is most satisfactory to cover bony prominences, scars, and so on. The edges should be chamfered.

Olive oil

In place of stockinet, olive oil may be used to prevent the plaster sticking to the patient s skin It is not possible however to mark the patient s skin with indelible

* Manufactured by the Medlock Manufacturing Co. Ltd Medlock Mills, Oldham, Lancs., England.

pencil and get these marks transferred to the positive cast when this method of skin protection is used

Making the casts

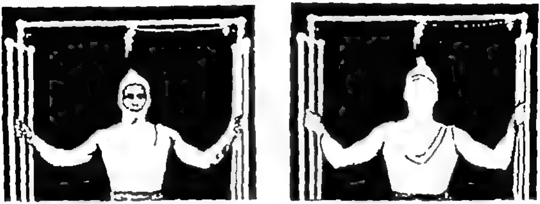
It is convenient to have all the material and equipment required for taking the cast on a table close at hand (Fig. 87)

A negative cervical cast is used as an illustration It is essential to have the part of the patient from which the cast is to be taken in the right position and having decided this, to make the patient as comfortable as possible Unless these

FIG 87 —Plaster trolley

elementary precautions are taken, it may be found that when the cast is set the position is very different from that which was intended If adhesive padding is being used this should be applied to areas over which pressure is to be relieved. The skin should then be protected with stockinet or oil If stockinet is used, the pressure areas and the outline of the final splint can be marked with an indelible pencil It is necessary to make the negative plaster cast more extensive than the final splint as to get a proper edge to any plastic moulding it has to be trimmed back, and if allowance is not made for this, too small a splint will result It is helpful to mark the outline of the extent of the negative plaster cast (Fig. 88*a* and *b*) A lead strip or rubber tube is held in position along the most convenient cutting line. A bandage is placed in a deep bucket, preferably rubber or polythene, and left on the bottom until all the bubbles have ceased to rise. Shallow containers are useless for plaster work, as a depth of water is needed to provide sufficient head of pressure to ensure proper wetting of bandages. On removal from the bucket the bandage should be gently pressed at the ends to expel surplus water On no account should the whole bandage be squeezed or wrung, otherwise the plaster will be forced out. The end of the bandage should always be found before

it is wetted. It is important to apply the first bandage with just sufficient tension to give a smooth surface in contact with the patient, taking care that no creases or tight bands are produced The cast should be made thick enough but not too thick, particularly along the cutting line No cast need be as substantial as a splint which is to be left on the patient. A thick cast is difficult to remove from



(a) (b)

FIG 88.—Patient with stockinet marked on front (a) and back (b). Outer line marking extent of plaster cast Inner line extent of polythene splint. Areas shaded to be built up on positive plaster cast to prevent undue pressure by the polythene moulding.

the patient. The edges of the cast should be of adequate thickness so that distortion does not occur when it is stood on its edge during drying out. Once the cast has set, which is best judged by tapping it with the knuckle, when it will have a woodlike ring, the cutting line is marked along the lead strip or tube and a number of transverse markings are made along this line (Fig. 89). The realignment of the transverse markings after the cast has been removed will ensure that the cast is bandaged into the correct position. A sharp leatherworker's knife is

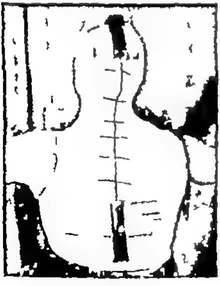


FIG. 89 —Cutting line over lead strip.

FIG. 90.—Reforming negative cast after removing it from patient.

the most satisfactory instrument to cut damp plaster. After removal of the cast the edge should be immediately realigned and a plaster bandage applied to retain it in the correct form (Fig 90) The negative cast should be dried in a warm place where there is adequate ventilation

Positive Plaster Cast

A coarse pink or white plaster is quite satisfactory for making positive plaster casts It may be necessary as is the case with negative cervical casts, to close in certain portions of the negative cast with plaster bandages. The inside of the negative cast may be wiped over with Vaseline or a light machine oil to make stripping of the positive cast easier, but this cannot be done if transference of markings from the negative cast is required The negative is then placed in a convenient position and filled with a thick plaster cream. Greased wooden mandrils of various sizes may be used to provide a central core which saves plaster and also aids in drying out the cast If these are not used, a metal rod should be inserted in the plaster and allowed to protrude for about 12 inches (30 centimetres) This is required for holding the cast in a vice during subsequent moulding operations. When the plaster has set the negative cast is stripped from the positive which is then corrected in the appropriate places This procedure requires considerable experience. In the initial stages of trimming and correcting a cast, a leatherworker's knife hacksaw blade, file and spokeshave will be found useful. Sand paper of various grades may be used to give a smooth surface finish if the plaster is dry (For more detailed information on the technique of plaster of Paris and the making of special casts, *see* Jordan, 1939 Nangle, 1951, and American Academy of Orthopaedic Surgeons, 1952.)

Resin Reinforced Plaster of Paris Bandages*

There has been and is a continual search for materials which can be added to plaster to improve the properties of plaster of Paris splints. Plaster is essentially brittle and when wetted it crumbles. Incorporation of melamine formaldehyde in ordinary plaster of Paris bandages gives them some of the advantages of glass acetate bandages (Morrison, 1953 Maudsley 1955) The water soluble melamine resins are either incorporated in the bandages or dissolved in the water in which they are immersed. On dissolving in the water and coming into contact with a suitable catalyst for example ammonium chloride, the resin polymerizes in a network around the wet plaster of Paris, giving it more strength and protecting it from softening when the dry cast comes into contact with water The slow setting time due to the resin can be adjusted by the incorporation of an accelerator in the bandage. Repeated contact with the bandages may cause dermatitis staff rather than patients are affected (Cobey 1954) For this reason those applying this type of bandage are advised to protect their hands with gloves or a barrier cream. Casts produced from resin impregnated plaster of Paris bandages can be made two-thirds the weight of the traditional plaster of Paris cast and yet have the same strength.

*Gypsona Extra manufactured by Smith and Nephew Ltd., Welwyn Garden City Herts., England.
Zoroc manufactured by Johnson and Johnson, New Brunswick, N.J., U.S.A.
Melmac manufactured by Davis and Geck, Brooklyn, N Y., U.S.A.

APPLIANCES MADE FROM PLASTIC MATERIALS

POLYTHENE MOLTOPREN LAMINATE SPLINTS *

These splints are made from sheet polythene (Scales, 1950a) to which is fused a sheet of polyurethane foam which provides cushioning between the skin and the splint

Polythene

Sheet polythene ⅛ inch and 3/16 inch thick is a most useful material for the manufacture of lightweight semi-rigid orthopaedic appliances. It is a thermoplastic material and has a moulding temperature of 140° C. For physical and chemical properties see Chapter 4. Polythenes of differing molecular weight are available It has been found that a grade having a melt index such that 1 7 to 2 3 grammes are extruded in ten minutes is most suitable (measured by the method described in Appendix A of the British Standard Specification 1973) Such a grade of material is known in Great Britain as Alkathene 2.† The use of polythenes of low molecular weight is not advised as they are liable to crack in use The sheet material used for surgical appliances ‡ is tinted pink by the addition of 0·01 per cent of a mixture of cadmium sulphide or cadmium sulphoselenide or both types of pigments it also contains 0 101 per cent of an antioxidant di orthoisocresyl propane Polythene is unaffected by fluids commonly used in industry it is a tough, resilient material which is particularly suitable for use on patients who are able to remain at work during their treatment. Temperatures below 100° C do not affect the appliances. Splints should not be placed in front of an electric fire or on top of a gas cooker as temperatures in excess of 100° C are easily reached and distortion of the appliance will result. While polythene can be ignited with difficulty—it burns with a yellowish smoky flame—the flame can be readily extinguished and its inflammability is in no way a hazard, since a flame has to be held in contact with the splint for up to a minute before ignition will occur This material has been used for splints for 8 years and no case of allergy or dermatitis is known. Occasionally patients who sweat excessively may complain of irritation but this is due to lack of ventilation holes in the splint or to inadequate washing of themselves or the splint. Excessive local pressure may cause reddening of the skin Carefully controlled local heating of the appliance may sometimes relieve this pressure, but unless extreme care is exercised, distortion of the appliance and possibly tearing of the polyurethane lining will result

Another grade of polythene which may be found useful for certain types of orthopaedic appliances is known as Ziegler § polythene or high-density low pressure polythene This material has different physical properties from those of the conventional high-pressure polythene of the type mentioned above It is more rigid and has a higher softening point, and thus Ziegler polythene splints may be made from thinner material and are lighter in weight. However the material is

* The use of polyurethane foams in combination with sheet polythene is covered by British Patent Nos. 748526 and 762897 which are held by the National Research Development Corporation, 1 Tilney Street, London, W 1 The use of polythene alone for orthopaedic appliances is not covered by patents.

† Manufactured by Imperial Chemical Industries Ltd., Welwyn Garden City, Herts, England

‡ Manufactured by Stanley Smith & Co., Worple Road, Isleworth, Middx, England.

§ The sheet material can be obtained from Stanley Smith & Co., Worple Road, Isleworth, Middx, England.

more difficult to manipulate and the attachment of polyurethane foams is at present not so easy as is the case with conventional polythenes The method to be described of forming splints is applicable when using Ziegler polythene providing they are of simple form right angled foot splints, for example cannot be made from Ziegler polythene by hand moulding

Polyurethane foam

Polyurethane foams are thermoset materials They are marketed by many companies in various countries and some products may be modified by the addition of undesirable plasticizers pigments, and other chemical agents. The foam is supplied

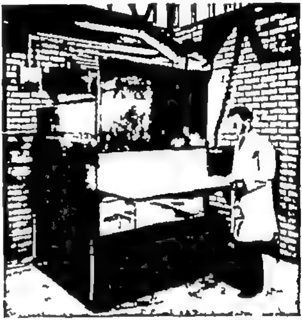


FIG. 91 —Infra-red heating oven.

in sheet form in thicknesses from $\frac{1}{16}$ inch upwards. Various densities of foam are available, the most satisfactory one for orthopaedic purposes having a specific gravity of between 0·055 to 0·065 * It is fully porous to water vapour readily compressed and almost non inflammable. The material is somewhat friable and splints lined with it should not be scrubbed Overheating or prolonged exposure to ultraviolet light causes the foam to discolour To mask the effect of ultraviolet light degradation, it has been found advisable to use pink tinted foams Temperatures up to 170° C do not affect its properties and when it is used in combination with polythene only distortion of its cellular structure occurs during moulding. Foams can be attached to polythene at 140 C without the use of adhesives. On cooling the laminate attempted removal results in rupture of the foam Because of its extremely low thermal conductivity polythene polyurethane laminates can be applied directly to the patient, providing the temperature of the polythene does not exceed 140° C The laminate is applied with the polyurethane in contact with the skin. If excessive pressure which would collapse the

* Trade name Foamoprene, reference No. 103/04/N Manufactured by Kay Brothers Ltd., Reddish, Stockport, Cheshire, England.

foam is used to form the splint, burns may result hence only splints having simple curves, for example cock up splints or leg gutters can be moulded with safety on the patient.

Equipment for the manufacture of appliances

The equipment required for making splints is minimal but it is advantageous for speed and ease of manufacture of appliances in quantity to have the following equipment

1 An infra-red process heating oven size 4 feet 6 inches by 4 feet 6 inches (Fig. 91) 48 × 250 watt internal reflector infra-red process heating bulbs will be required to cover 8 square feet. They should be held in suitable holders to give adequate ventilation of the stems of the bulbs and to give a clearance between the bulbs and the asbestos covered floor of the oven of 12–14 inches. Since polythene is a poor heat conductor and the lamps give a high surface temperature, it is advisable to switch the current on and off intermittently by means of a time cycling device. Suitable ovens are now commercially available. Various other types of gas or electric ovens can be improvized but it is essential that even heating of the polythene is obtained and that the temperature of the material does not rise above 150° C. Experimental work with porous plastic suggests that a hot-air circulating oven may be a more suitable way of heating these materials.

2. A foot-operated punching and riveting machine with a throat of not less than 12 inches. 1/8 inch, 3/16 inch and 1/4 inch punches are required. This machine can be used for the insertion of tubular rivets, eyelets, press studs, and for punching ventilation holes (Fig. 92) the latter operation should be done from the foam surface of the appliance.

3 A bandsaw for cutting the polythene. This machine should have a throat of not less than 12 inches.

4 A 6-inch soft wire mop and sanding discs attached to a standard double-ended polishing head.

5 A leather worker's knife and whetstone.

6 Ribbed surgical stockinet, width 12 inches, as used for plaster work.

7 A medium to coarse metal file and various grades of sandpaper

FIG. 92.—Perforating appliance.

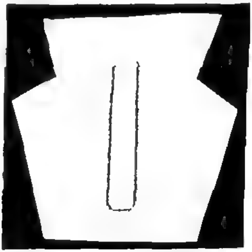


FIG. 93—Material for one half of cervical collar prior to heating.

Forming the splints

Using polythene–polyurethane laminates simple splints such as leg gutters wrist cock-up splints, or small back supports may be formed direct on the patient (Van Swaay 1954 Brennan 1955 McKee 1956) For larger splints, such as spinal jackets, long leg splints, cervical collars and hip spicas a positive plaster cast is essential A piece of polythene of the appropriate size is cut with the band saw or less easily with a sharp leather knife If a knife is used care should be taken that cuts are not made in the polythene by the knife as these can cause subsequent cracking in the material Such cracking is more liable to occur following knife trimming of the splint after moulding The direction of pull of the knife should always be away from that part of the sheet which is to form the splint. The polythene should be washed with warm water and soap so as to remove any dust or grease which may contaminate the surface and prevent adhesion of either

Fig. 94 —Moulding back half of cervical collar

the reinforcing strip or the polyurethane A sheet of the foam the overall dimensions of which are about ½ inch to ½ inch greater than those of the polythene sheet, is placed in the oven and covered with the polythene Reinforcing strips of polythene which are obtained from offcuts are placed in the appropriate positions on top of the polythene (Fig. 93)

To establish the working conditions for a particular oven, the time–temperature relationship should be recorded by inserting in the sheet of polythene a thermocouple connected to a pyrometer The temperature of the polythene cannot be recorded by placing mercury thermometers on the surface of the sheet if infra red heating is employed. When the polythene is ready for moulding, both the reinforcing strip if present, and the main sheet of polythene should be transparent If any bubbles occur between the reinforcing strip and the main polythene sheet they should be pricked with a pin to let out the air A piece of stockinet is applied using light pressure, to the surface of the polythene The stockinet should not be unduly stretched and care should be taken to see that creases are not produced The stockinet-polythene polyurethane laminate is lifted from the oven and is applied to the plaster cast (Fig 94) It is then gently stretched into position and a

few nails are driven into the cast through the moulding at convenient points to hold it in position. When the moulding has cooled, the stockinet is stripped from the surface of the polythene and the splint removed from the cast. The edges are trimmed, ventilation holes are punched in appropriate places and buckles and straps riveted in position. Ventilation holes, ¼ inch in diameter should be drilled or punched in areas which are carrying a load, in other parts of the splint larger holes may be made. Leather or plastic tongues where the splint edges come together in encircling splints should be attached to prevent nipping of the skin.

When moulding small splints direct on the patient the operator should always check that the laminate is not excessively hot by resting the foam side of the laminate on the back of his own hand for a few seconds prior to moulding it on the patient. For patients who may be apprehensive of this procedure, a sheet of

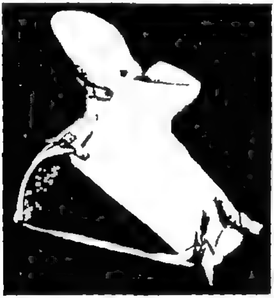


FIG. 95.—Completed cervical collar

$\frac{1}{16}$ inch polyurethane may be applied to the patient and held in position by adhesive tape prior to forming the hot laminate. The laminate is then moulded by applying evenly wet 2 inch cotton bandages.

At body temperature the splint has slight resilience, but is not readily deformed. Polythene-polyurethane appliances can be made more quickly and more simply using the technique described, than moulded leather or cellulose acetate splints reinforced with metal. For example a cervical collar (Fig. 83) including the time spent in taking the positive cast, can be made and supplied to the patient in 2½ hours. Metal reinforcement is not required. The splint is light in weight, durable and washable. Ventilation holes must be kept clean and the foam sponged regularly. After washing, the surface should be pressed with a sheet of blotting-paper dampened with methylated spirit. Blotting paper without spirit and a dry towel will remove excess water but the splint may feel damp when applied. If too much spirit is used, swelling of the foam will result.

Cotton-cellulose Nitrate Fabric (Samcoforma) *

This material is suitable for certain types of non weight bearing appliances The moulding fabric, which is available in seven thicknesses varying from 0·025 inch to 0 128 inch consists of a double raised cotton material which has been impregnated with a dispersion of cellulose nitrate—plasticized with camphor—and gypsum which is added as a fire retardant. The fabric as supplied and after evaporation of the solvent used to soften the sheet for moulding, will not ignite unless in direct contact with a naked flame or metal at red heat, when it will burn with a slow flame.

Manufacture of appliances

A positive plaster cast is required The cast is lightly smeared with petroleum jelly or a good quality floor polish which acts as a parting agent and prevents the fabric from sticking to the positive cast The requisite number of sheets are cut out, allowing 1 inch over the measurements which are required for the finished splint. Each sheet is immersed in a suitable ketonic solvent—higher ketone solvents being most suitable—for not more than 5 or 10 seconds The fabric is wrapped around the cast the overlap being arranged where the lacings or fasteners will be placed Should the material start to harden, a little extra solvent should be applied with a brush. For certain splints such as for the wrist one layer of the thick material will be sufficient. For larger splints a second layer may be added, or strips of the material may be applied where additional strength is required. On re-entrant curves, a cotton bandage may be applied to hold the fabric in position. The edges of the moulding are held in position by means of tacks Bonding of layers of the fabric is best achieved by the use of a roller of suitable width. The moulding should be left *in situ* for at least 12 hours, after which an opening cut is made down the line of overlap either with an electric circular hand saw or a sharp leather knife It is advisable to allow the cast to dry for a further half hour after removing it from the plaster of Paris positive cast, with the edges of the opening cut clamped together to prevent curling of the splint. After the splint has been fitted to the patient, ventilation holes are punched and the inside and outside surfaces of the splint are smoothed with coarse and fine sandpapers A suitably plasticized, flesh coloured cellulose lacquer is applied on the outer surface and to the inner surface if the splint is not to be lined. Two or more coats of the lacquer may be required about 15 minutes should be allowed for drying between the application of each coat. The splint may be lined with chamois leather Buckles lacings or zip-fasteners are then attached

It is advisable for those in continuous contact with the material to use a barrier cream or rubber gloves, since the solvent is inclined to dry the skin. Moulding should be carried out in a well ventilated area, as inhalation of ketones may cause headaches and nausea All ketones are highly inflammable

Appliances made from this material are light in weight and resilient and can be supplied to the patient in a shorter time than moulded leather or cellulose acetate appliances. They are not however as robust as those of polythene

* Manufactured by B.U Supplies and Machinery Co Ltd., Leicester England. Distributed by Ellis Son and Paramore Ltd., Sheffield, England.

Cellulose Acetate Splints *

Cellulose acetate in combination with muslin was one of the first plastic materials used for making orthopaedic appliances. Newer materials, for example polythene have taken its place

However no apparatus is required for making these light-weight appliances and therefore their method of manufacture is given. A dry cast of the part is prepared in the usual manner The surface should be quite smooth and liberally dusted with French chalk. The cellulose acetate solution may be prepared by dissolving washed radiological or photographic film in acetone until the consistency of the solution is equivalent to that of good quality oil paint Some types of radiological film will not dissolve. Cellulose acetate chips can be obtained and these will be more satisfactory to use than scrap film. A layer of unstarched butter muslin is applied to the cast and the cellulose acetate solution brushed on with a stiff hairbrush. Another layer of muslin is added and the process repeated. Upwards of 20 layers of muslin may be required for large splints. Extra strips of the material are placed in potentially weak areas. It is advisable to let the acetate practically dry before the application of each layer otherwise the evaporation of the solvent from the laminate will be unduly prolonged. It is essential to avoid air bubbles and to ensure that each layer of muslin is completely in contact with the layer beneath. To prevent the formation of voids, the muslin should not be stretched across re-entrant curves. The completed laminate should be allowed to dry for about 48 hours before it is split and sprung off the cast. It is not as a rule necessary to bivalve the splint. It should then be fitted to the patient, marked and trimmed with either a sharp knife or an electrical handsaw As soon as fitting is completed, the splint should be reapplied to the plaster cast, otherwise the continued evaporation of the solvent will cause curling. Ventilation holes should be drilled before lining and coating the splint. When evaporation of the solvent is complete, the inner surface may either be lined with chamois leather or painted with a further coat of acetate solution. The edges of the splint are bound with leather and lacings or straps and buckles fitted. Large splints usually require metal strips to be riveted across weak areas. Cadmium-plated rivets should be used for attaching fittings. The finished splint is light in weight and, if unlined, easy to keep clean. If the splint is constantly flexed, however or the edge is sat upon, as is often the case with spicas, cracking of the appliance is likely to occur These cracks may be repaired by the application of muslin and further cellulose acetate solution.

Cellulose Acetate Glass Fibre Bandage †

This bandage was described by Kulowski French and Erickson (1944) It consists of a knitted fabric the constituents being approximately glass fibre 20 per cent and cellulose acetate 80 per cent by weight.

When dipped in a volatile solvent the acetate fibres swell and partially dissolve. The solvent, which is inflammable, is a combination of acetone, methyl salicylate and a group of hydrocarbons, the exact proportions being the subject of industrial patents. Great care must be taken when the cast is drying that the patient is not exposed to a toxic concentration of vapour as may occur under the bedclothes, particularly when a heat cradle is in use (Renshaw and Mitchell 1956). Naked lights and hot-wire elements in hair driers must be avoided, otherwise a fire may result. Once the cast has dried its inflammability is no greater than that of wooden splints. Setting fluids remove the fats from the skin and the operator is advised to apply a barrier cream to the hands. This precaution is not necessary as far as the patient is concerned as there is practically no free fluid escaping from the bandage when it is applied.

* Celluloid is the name used for cellulose nitrate, a highly inflammable plastic material which should never be used for this type of splint. Appliances made from cellulose acetate should not be termed "celluloid splints."

† These bandages are marketed under the trade name of Glassona by Smith and Nephew Ltd in Great Britain, and in the United States of America under the trade name of Altro-cast by the Tower Co Inc Seattle.

Technique of application of bandage

The part which is to be immobilized should be covered with a layer of stockinet of sufficient extent to turn back over the cast so as to form a smooth edge. The bandages are immersed in the setting fluid and immediately withdrawn and applied under slight tension. Several layers of bandage will be needed to give adequate strength. Care should be taken that the outer layer is smooth moulding being facilitated by applying a crepe bandage for 1 to 2 minutes. It is never advisable to apply the acetate glass bandage direct to the skin.

It is most important that the flat of the hand and not the fingertips are used for moulding, otherwise pressure areas will be formed in the dough-like material The splint will become reasonably rigid in about half an hour but since the inner layer of the splint will be soft the cast may deform if pressure is applied locally during the first 24 hours. Casts made from this material are light in weight strong and resilient unaffected by water and excreta and translucent to x-rays They are porous to a variable extent to water vapour Bandages may be stored without fear of damage by moist atmospheres.

POLYMETHYL METHACRYLATE

(PERSPEX, PLEXIGLASS OR LUCITE) *

Perspex is available in either transparent or opaque sheets 48 inches by 60 inches from $\frac{1}{16}$ inch to $\frac{1}{2}$ inch thick The plasticized material (plasticized with dibutyl phthalate) is most satisfactory as it moulds more easily and has a somewhat higher impact strength

The requisite size of sheet to form a splint is tailored to the measurements of the cast. In 1943 McGowan described the use of Perspex for certain limb gutters by forming the material on positive plaster casts. With large splints however the hand method is not adequate. Scales and Herschell (1945) described a method using compressed air to form Perspex inside reinforced negative plaster casts. The apparatus required was complex and expensive and could only be used in specialized centres. A major disadvantage of Perspex splints is that, should they break the edges are sharp and can penetrate the skin causing considerable damage. The large appliances are too rigid since $\frac{1}{16}$ inch material has to be used. Polythene is far more suitable than Perspex, which is difficult to form even into such simple shapes as cock-up splints. (For the manipulation of Perspex *see* Nangle 1951)

VINYL POLYMERS

Polymers and copolymers of vinyl chloride in sheet form have been used experimentally for various orthopaedic appliances They are suitable for the simpler types such as long leg gutters and cock up splints The polymers are all thermoplasts and can be moulded in the same way as Perspex They have a moulding temperature of between 70° and 120° C, depending on the type of polymer Up to the present time the most suitable material has been a copolymer of vinyl chloride and vinylidene chloride † It has a moulding temperature of approximately 120° C and care should be taken that it is not overheated The material

* Perspex is manufactured by Imperial Chemical Industries Ltd., Welwyn Garden City Herts, England.

Plexiglass is manufactured by Rohm Hass & Co., 222 West Washington Square, Philadelphia, U.S.A.

Lucite is manufactured by E. I. Dupont de Nemours Co Inc. (Plastics Division) 626 Schuyler Avenue, Arlington, N.J., U.S.A.

† This material is manufactured by BX Plastics Ltd., London, England, under the trade name of " Cobex," 5004 PINK " S " Surface Z grade.

cannot be moulded direct on the patient. A sheet ⅛ inch thick has been found suitable for all types of simple splints. The material can be softened in an infra red heating oven. It is advisable to use a dry warmed cast, otherwise chilling of the material will occur and moulding will be very difficult. After applying the softened sheet to the cast which should be done as quickly as possible, a piece of stockinet is stretched over the moulding and the ends of the stockinet anchored by driving nails into the plaster cast through the stockinet. It is important that an even tension of the stockinet is maintained. When the material is cool, the moulding can be removed from the cast and trimmed to size with an electrical handsaw—it cannot be cut with a leatherworker's knife. If buckles and straps are to be attached by rivets clearance holes should be drilled in the appliance. Great care should be exercised in all riveting operations, otherwise splitting of the material will result. Ventilation holes ⅛ inch in diameter are required as the polymer is virtually non porous. Splints are light in weight and considerably more rigid than similar appliances made from polythene. They are unaffected by water and body secretions. Patients should wash the appliance regularly. Polyurethane foams will not adhere to the softened material but can be attached afterwards by painting the inner surface of the appliance with a suitable adhesive however this procedure is not recommended since a good bond between the foam and the splint is difficult to obtain. If this method is practised a non-dermatitic adhesive must be used.

Resinated Asbestos Felt *

This material is an asbestos felt which has been impregnated with a partially condensed phenol formaldehyde resin. With the application of heat, further condensation of the resin takes place with the liberation of water resulting in a thermoset plastic. In the manufacture of the felt, the asbestos fibres come to lie in the same direction, thus the felt can be stretched with the grain of the fibre but tears if pulled across the grain. The thin and medium thickness sheets are the most useful for moulding. The resin content and type of fibre vary with the grade, RA1 being the most suitable material for orthopaedic appliances. The felt should be stored in a dark cool place (not above 7° C) and be kept in the original packing to prevent excessive drying out. The material tends to harden when stored, but even after 2 years it can still be used providing the conditions of storage are observed. As the uncured material contains phenol and formalin, skin irritation may be caused in susceptible persons concerned with its handling or manipulation this trouble can be avoided by using a barrier cream. The cured material of the finished splint is non-irritant.

Method of making a splint

The material is most suitable for making rigid appliances, such as pylons (Fig. 96) limb gutters, and so on (Scales, 1950a). A positive plaster cast is required as the material cannot be moulded direct on the patient. The plaster cast should be painted with a solution of cellulose acetate to prevent adhesion of the cured

* Made by Turner Brothers Asbestos Co. Ltd., Rochdale, Lancs, England, under the trade name "Durestos". There are three standard grades RA1 RA3 and RA9 each in three thicknesses.

moulding. When the acetate is dry a film of petroleum jelly is applied For the manufacture of an above knee pylon either a positive cast or an adjustable metal former may be used The appropriate number of pieces are tailored from a sheet of felt of the desired thickness The felt should be dampened either with water or methylated spirit to facilitate moulding and bonding of the layers The first sheet should be applied right round the cast and the edges teased out so as to make a good

FIG. 96.—Bilateral pylons with simple knee hinge right limb, used in the treatment of an achoodroplasiac who had below-knee amputations.

joint. It is desirable to so tailor the felts that they can be applied with the grain in successive layers at right angles to each other An adhesive, Aerodux 185 * which gives the cured laminate improved mechanical properties, may be applied between the layers of felt. It is important to make sure that no air is trapped between the felts and a rubber or metal disc type roller may be used to ensure that all the layers are well bonded Reinforcing strips of felt may be added wherever increased local strength is needed The last felt should be completely encircling and cover all reinforcing strips An open wove cotton bandage is applied under tension round the moulding care being taken that when applying the bandage the felts do not slide and buckle with the formation of air pockets

* Made by Aero Research Ltd., Duxford, England. This adhesive is a resorcinol formaldehyde resin, activated by the addition of one-fifth by weight of paraformaldehyde. Furfuryl alcohol 1 to 2 per cent is added after compounding, and this aids in the dispersion of the adhesive through the felt. (L. N Phillips, Royal Aircraft Establishment Farnborough *British Plastics*, October 1949 page 535)

The moulding should be left to dry for an hour or two and then painted with a viscous solution of cellulose acetate. As the solvent evaporates, a skin is formed which contracts on to the felt and gives a smooth surface finish. The appliance is now placed in a gas oven with the thermostat set at 75° C and allowed to cure for approximately 8 hours. It is important that the oven is not of the sealed type otherwise water vapour from the cast and the laminate cannot escape and curing of the moulding will be delayed. At higher temperatures delamination occurs due to the steep rise in the water vapour pressure above this temperature. When cured, the appliance is removed from the former and fitted to the patient. If ventilation holes are required, they are drilled at this stage. The inner surface is coated with an unplasticized water emulsion of polyvinyl acetate * which on heating for a few minutes in an oven at about 95° C forms a continous transparent film.

The outside of the appliance should be coated with an aluminium paint and then sprayed with a flesh-coloured cellulose lacquer. It is essential to use a metal-based paint as a primer to prevent undue absorption of the cellulose lacquer by the laminate. Durestos appliances do not require metal reinforcement; they are durable, light in weight, do not distort with use; they are washable and unaffected by sweat, urine and faeces, non inflammable, and can be produced at low cost.

POLYESTERS

These resins are used in the manufacture of paint, for electrical insulation, hulls of boats, car bodies and aircraft components. Their chemistry is dealt with in Chapter 4. They can be considered as thermoset resins which are formed by the cross-linking of a liquid thermoplastic resin, the usual cross-linking agent being styrene, although recently monomethyl methacrylate has been used. Considerable efforts have been made in the past to use these resins for orthopaedic purposes, since they possess the following characteristics:

1. During polymerization no by products are produced.
2. The polymerization can be made to occur at room temperature by the use of suitable catalysts and activators.
3. The rate of polymerization can be varied by adjusting the amount of catalyst used.
4. Pressureless moulding techniques can be employed.
5. The viscosity of the resin can be varied by altering the proportions of the monomer and alkyd part of the resin.
6. They can be used in combination with a variety of reinforcing agents such as glass fibre or cotton.

In spite of the obvious advantages which they possess, they also have certain disadvantages. They are sticky, somewhat viscous liquids which must be used in combination with a reinforcing agent, the one with the best mechanical properties being glass fibre. The monomer or cross-linking agent, which is usually styrene, has been said to cause skin irritation and it is necessary for those who are constantly using the resins to apply a barrier cream. The polymerization or curing of the resin is an exothermic reaction and if sufficient catalyst is added to enable the reaction to occur in a reasonable time (15 minutes), the heat produced may burn

* Available under the trade name "Revertex". Supplied by Revertex Ltd., London, England.

cast has been well prepared and the release properly applied, the inside of the socket will be smooth. Air trapped beneath the first layer of glassmat or a lump of polish may cause indentation of the laminate which will require smoothing and possibly recoating with resin.

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CHAPTER 20

STERILIZATION

R. Knox

INTRODUCTION

Until quite recently most surgeons were apt to take sterilization for granted and were concerned about it only if something serious seemed to have gone wrong. The coming of antibiotics perhaps encouraged this attitude since by the use of the appropriate antibiotic " umbrella " it became for the first time possible to carry out successfully and with little risk of infection many operations which formerly had a high fatality from septic complications. But in the last few year there have been signs of a renewed interest in the efficiency of our methods of sterilization. This has been due partly to the obvious limitations of antibiotics in preventing surgical infections, partly to increasing evidence that many times honoured methods of sterilization simply do not sterilize and partly to the increasing fear of litigation following surgical disasters.

Frequency of surgical infections

Very few reliable figures are available as to the frequency of surgical infections (Howe, 1954). When trivial infections occur it is often impossible or it may not be thought worth while, to find the true source. Even with serious or fatal infections the source may not be found because there are so many possible avenues of infection Infection occurring in surgical wards is often due to faulty techniques in medical or nursing care or various breakdowns in hygiene either in the theatre or in the ward (Devenish and Miles, 1939 Blowers and his colleagues, 1955 Colbeck, 1956 Hare and Thomas, 1956 Shooter and his colleagues, 1956 Shooter and his colleagues, 1957) It is not often that infection can be clearly traced to a breakdown in sterilization (Sevitt, 1949) more frequently there is a general overhaul of all techniques, including sterilization methods, and no fresh infections occur perhaps for a long time. Surgical technique today is like modern hygiene—the average standard seems to be so high and obvious failures are so comparatively rare, that it is difficult to raise any enthusiasm for schemes for turning something good into something even better; such schemes are likely to be very expensive In some developing fields, however such as neurosurgery and skin grafting, disaster may result from infections which would be trivial in other situations

It is against this background that methods of sterilization must be considered. The methods available and their correct use are briefly reviewed, their advantages and disadvantages discussed, and an attempt made to outline the rules which must be observed if sterilization is to be effective.

Errors in sterilization practice

Some important sources of error in sterilization practice should be emphasized at this stage (Perkins, 1956) In most sterilization procedures in common use

today the sterilizing agent is applied for a defined period of time generally accepted as being safe This must not be confused with the minimum time necessary for the same agent to kill organisms in experimental conditions For example, it is probably true that spore suspensions of most bacteria will be killed in 4–5 minutes if they are exposed to steam under pressure at 121 C (15 pounds pressure of pure steam) provided the spores themselves are at that temperature But if the same spore suspension was wrapped tightly inside a thick package of surgical dressings in an autoclave filled deliberately to the brim so that steam (and heat) could hardly penetrate at all it might take a very long time to kill the spores. It is generally agreed that material for sterilization must not be too tightly packed and in many hospitals great attention is being paid to this but in many others it is still neglected and tight packing is the rule rather than the exception. Even with loose packing accumulated small errors could result in failure to sterilize—errors in timing faulty recording of temperature or pressure variation in the source of heat and rate of heating, and permissible variations in the type of load. There must be an ample margin of safety to cover all these, and the times and temperatures necessary in practice are considerably greater than the minimum necessary in ideal experimental tests. This means that many materials which are easily damaged have their effective life shortened by repeated exposures, and great economy would be achieved if exposure times could be cut down without loss of safety Research in this field is urgently needed and would undoubtedly be worth while.

On the other hand there is no doubt that many of the times and exposures currently used in practice are too short for safety It must be remembered that sterilization as commonly used can never be quite instantaneous. A given amount of heat or a given concentration of a disinfectant may kill a large proportion of the organisms in a culture very rapidly but the time required for killing *all* the organisms is very much longer For example boiling water has for long been accepted as a safe method of sterilization But its safety depends on the way in which it is used If clean instruments are dropped (not more than a few at a time) directly into boiling water most of the non-sporing bacteria which are likely to be on them will be killed in 5 minutes or less. But the same bacteria inside a syringe, or heat resistant spores will certainly not be killed and even much longer periods of boiling would be unreliable If in addition the bacteria are embedded in dried pus blood or other material, then any method of sterilization becomes much more unreliable

The fact is that many of the exposure periods used today which have become part and parcel of surgical practice have been adopted without really critical or exhaustive trial. Most of them have appeared to be successful in routine use, and this feeling of confidence has been encouraged by the rarity with which sepsis has been traced to breakdown in sterilization *Bacteriological evidence has* seldom been produced and much of what has been produced is of considerable antiquity It may be true that even if small numbers of bacteria survive so-called sterilization the body defences can usually dispose of them But the object of sterilization is to sterilize and anything less is failure.

It is usual to distinguish between sterilization and disinfection. By sterilization is meant the destruction of all living micro-organisms. The word "sterile" therefore should be used for surgical instruments and equipment only when these

have been properly sterilized and maintained in that state up to the moment of use Disinfection on the other hand means the removal of all organisms which are likely to cause infection Many methods of disinfection are effective and safe enough for everyday use but they are not methods of sterilization and should never be so described

The main methods of sterilization are mechanical chemical and physical

MECHANICAL METHODS

Of mechanical methods the most important is filtration in which materials are passed through suitable filters which remove micro-organisms partly by mechanical means and partly by means of their electric charge In surgery there are two main applications of filtration—in sterilizing materials such as sera and other biological liquids which would not withstand more drastic physical or chemical treatment, and in sterilizing contaminated air For the filtration of liquids a variety of filters are used—sintered glass, Seitz asbestos pads, porous candles such as Berkefeld, Chamberland or Doulton or membranes of collodion or other materials. Filters differ greatly in their porosity and in the purposes for which they are suitable Those of large pore size do not sterilize at all. They are often used to clarify a liquid before it is passed through a sterilizing filter or finer pores which would otherwise be clogged up It is essential to make sure that the filters used are the correct ones for sterilization and that all apparatus is properly assembled, sterilized and used by trained staff Filtration of air is especially important in operating theatres and other places where contaminated air is dangerous In coming air is passed through dust filters of various kinds or over electrically charged plates which remove bacteria laden dust particles Air filters are liable to get blocked, especially in smoky cities and need to be frequently changed and carefully maintained by skilled staff who understand the problems involved Clogged, inefficient filters are not only useless but positively dangerous

CHEMICAL METHODS

The number of chemical substances used for " sterilization " is enormous. None is entirely satisfactory and as a general rule it may be said that chemical methods aimed at sterilization should be used only when other methods are not available The common practice of rinsing or even of preserving instruments or glassware in disinfecting fluids from which they are removed to be used, with or without rinsing in so-called sterile distilled water is unreliable and dangerous If disinfectants must be used in an emergency the following rules should be observed all articles to be disinfected must be thoroughly cleaned first, they must be completely immersed for an adequate length of time in a disinfectant solution whose strength can be relied upon and the times and concentrations necessary for safety must be determined for each disinfectant by direct bacteriological tests carried out by a competent bacteriologist.

Chemical substances may also be used in the form of gases or vapours Formaldehyde (CH_2O) vapour has been used for many years in attempts at terminal disinfection of rooms air furniture and other equipment which cannot be conveniently moved or sterilized by heat It is now realized that the old method of

burning formalin candles is useless unless the air is moist and that water vapour must be present if formaldehyde is to exert its full effect. Formaldehyde vapour has also been used for treatment of mattresses and other materials in large disinfectors which can be filled with the vapour It is reasonably efficient at disinfecting surfaces, but its power of penetrating into the inside of mattresses and other articles is erratic and in any case the vapour is irritating if it is not thoroughly removed. Ethylene oxide $(CH_2)_2O$ is a very effective bactericidal substance. Mixed with carbon dioxide it is safe and non inflammable but mixed with air it is explosive It is being developed in some countries and has certain great advantages, as it is much more easily removed and has much greater penetrating power than formaldehyde

It seems likely that whereas formaldehyde is a useful disinfectant for many purposes but is not to be regarded as a good sterilizing agent, there is a definite place for ethylene oxide for true sterilization and its range of usefulness is likely to increase in the future (Perkins, 1956)

PHYSICAL METHODS

Heat

Of physical agents heat is the one most commonly used. It may be applied as moist or dry heat, and the various forms have different advantages for different types of material. The most commonly used methods of sterilization by heat are (1) Steam under pressure (2) hot air (3) immersion in boiling water (4) exposure to free flowing steam.

Steam under pressure

Provided it is properly used, steam under pressure is probably the most reliable and efficient method of sterilization known Its great efficiency depends partly on the attainment of temperatures higher than can be reached by boiling or by steam at atmospheric pressure but even more on the great penetrating power of saturated steam due to its latent heat. Bacterial spores which can withstand 2–3 hours of exposure to dry heat at 121 C may be killed in a few minutes by exposure to the same temperature in the presence of saturated steam at 15 pounds pressure

The essential object in a pressure steam sterilizer is quite simply to deliver saturated steam in such a way that the required temperature can be rapidly reached accurately maintained and quickly reduced when sterilization is finished. The achievement of this object can best be considered under two main heads—the design and maintenance of the apparatus itself and the proper preparation, packing and sterilization of the materials put into it.

The design and maintenance of pressure steam sterilizers—The great efficiency of pressure steam sterilization cannot be fully exploited unless a good deal of skill and intelligence have been used both in the design and in the operation of the apparatus Many varieties of apparatus at present in use are badly designed and difficult to maintain, and their operation is often left in the hands of unskilled staff who do not understand the principles and purpose of steam sterilization There are two main groups of defect—errors in basic design and failure to record accurately pressures and temperatures attained

Errors in design—The most serious error in basic design is the failure to provide

for rapid removal of air and for its rapid replacement by pure saturated steam even with the apparatus empty When steam at a pressure of say 20 pounds per square inch is let into the main chamber which contains cold air unless the air is rapidly removed layering will occur and there may be large differences of temperature between the steam at the top of the apparatus and a cushion of air in the lower half When the chamber is loaded with solutions to be sterilized the temperature difference between the top and the bottom of flasks or bottles may be great enough to cause a horizontal fracture This pocketing of air can be avoided only by providing efficient methods for its rapid removal as the steam flows in Air may be removed either by downward displacement or by the use of vacuum Air is heavier than steam and for downward displacement the air outlet must be at the bottom of the apparatus and at the opposite end from the steam inlet, so that there is a steady flow of steam pushing the air out from one end to the other of the chamber The air outlet must therefore be wide and unobstructed and its proper maintenance is vital Since the exhaust line is likely to be the last part of the apparatus to reach the temperature of the incoming steam it is here that a thermometer should be situated (Perkins, 1956)

The vacuum method of removing air is perhaps more commonly used either by making use of the partial vacuum which can be produced by using the steam pressure to withdraw air from the chamber or by the use of a vacuum pump There is a good deal of disagreement as to the best method of removing air but the method whereby a vacuum of 10 inches or at the most 20 inches is created in the chamber by means of the steam is probably the least efficient. Whatever method is used, it is essential that there should be a free flow of advancing steam to push out the last traces of air and that sterilization should not start until the chamber is filled with pure saturated steam at the required temperature

Errors in recording temperature and pressure —Modern steam pressure sterilizers are fitted with instruments which record the temperature reached in the main chamber of the apparatus, but older sterilizers recorded only the pressure not the temperature attained To rely on readings of pressure alone can be disastrous in at least two ways. Many pressure gauges are at best not very accurate and if they are not working properly may be grossly wrong. If therefore a pressure gauge is reading too high a reading say of 15 pounds per square inch may be thought to indicate that a temperature of 121 C (which is the temperature of pure saturated steam at 15 pounds pressure per square inch) has been attained or maintained in the sterilizer But if the true pressure were not 15 pounds but only 10 pounds per square inch, the temperature reached in the sterilizer would be only 115 C, a temperature which would not effectively sterilize in the time recommended for a higher temperature. A second reason for not relying on the pressure gauge alone is that a certain pressure of steam indicates a certain temperature only if the steam is pure and not mixed with air Even if the pressure gauge is accurate there must be certainty that all traces of air have been expelled from the chamber of the sterilizer Otherwise the true temperature in the sterilizer may be a good deal lower than the pressure would suggest. It is also unsafe to rely on recordings of temperature alone It is possible particularly if there is a high pressure of steam in the jacket, for the steam in the main chamber to become superheated Small amounts of superheating do no harm (Savage 1937) but excessive superheating is undoubtedly bad since it means that use is not made of the full penetrating power

of saturated steam, and conditions are nearer to those of dry heat rather than of saturated steam.

The only way to avoid these errors is to make sure that the apparatus is provided with instruments for observing (and preferably recording automatically as well) both pressure and temperature. If the apparatus is working properly for every change of pressure there will be a corresponding change of temperature in the chamber Any discrepancy between pressure and temperature will at once be observed and an explanation for it must be found Thermometers and gauges must be frequently checked and their performance maintained.

Loading of pressure steam sterilizers—Correct design and operation of the apparatus itself are important, but no sterilizer will do its job properly unless care is also taken in the preparation loading and control of the apparatus during actual sterilization. Here again the first essential is to allow for the free penetration of saturated steam into all parts of the material to be sterilized. It is now well recognized that even with the most efficiently designed and maintained apparatus, sterilization will fail if the chamber is crammed full of dressings in which air pockets collect. A large tightly packed surgical bundle can cause obstruction of the flow of steam so great that the centre may take hours to reach sterilizing temperatures, and sporing organisms may completely escape destruction. Different sterilizing times and temperatures are necessary for different types of material. Some materials—for example, rubber gloves—are so easily ruined by excessive heat that it is doubtful whether any method of sterilizing them is completely reliable and it is obvious that bulky dressings need a longer time than smaller articles even when there is no question of excessively tight packing. In the case of liquids the volume is obviously important. Even in a fully efficient steam sterilizer in which a sterilizing temperature of say 121 C is rapidly reached, it will take much longer to sterilize 10 litres of saline in one large flask than if it were distributed without overcrowding in a large number of smaller bottles (Perkins, 1956)

These facts lead to several important conclusions The time and temperature suitable for sterilizing a variety of different loads must be determined for each new sterilizer A good deal of information is already available as a guide, but a few preliminary tests with full bacteriological controls must be carried out before any new sterilizer is put into service. Ideally the following tests should be carried out (1) A record of temperature and pressure in the chamber itself and especially of the temperature in or near the discharge line. (2) A record of the temperature reached in the most inaccessible part of dressings or other materials being sterilized. For this purpose it may be necessary to have a dummy dressing within which a thermocouple or resistance thermometer can be inserted, giving a continuous record of temperature. (3) Since this is not usually feasible simpler but cruder tests are often done with coloured liquids or other materials which change colour only if the temperature has reached a certain level for a certain time. These are very suitable for routine checking and, despite certain disadvantages, seem to be fairly reliable If a completely reliable colour control material could be found this would make a great advance in sterilization practice. (4) Bacteriological tests should be carried out to see whether spores in the centre of dressings or other materials are in fact killed during the period of exposure

At first sight it would seem that this must be the ultimate test since destruction of all living organisms is the objective But bacteriological tests, important

though they are must be viewed in proper perspective The conclusions to be drawn from them depend on the heat resistance of the test organism on the concentration of organisms used and on the way in which they are exposed to the sterilizing agent. Some spores are so resistant to heat that any process which had to guarantee that they would be killed would be seriously damaging to many materials. Other spores may not be resistant enough and if these are used as test organisms there may be no guarantee that spores of pathogenic organisms have been destroyed A disadvantage of bacteriological tests is the delay necessary before results can be known This means that they can never be used as routine tests on the results of which loads which have been sterilized can be accepted or rejected for immediate use. But, taken in conjunction with other tests, they are of great value and especially when carried out by a bacteriologist who is familiar with the apparatus and its operation and is not just reporting from his laboratory about an apparatus that he has never seen

Some disadvantages of high pressure steam sterilization—The advantages of pressure steam sterilization have been repeatedly emphasized It has however certain disadvantages which arise from the very nature of the process. Since the whole purpose is to expose the material to be sterilized to saturated steam the method is useless for sterilizing empty jars bottles or other containers with steam tight lids, since no steam can penetrate into the inside of the container Any sterilizing that is achieved will be due solely to the temperature attained and not to the penetrating power of steam If only a small volume of a watery fluid is in the containers the situation is quite different, since enough steam is generated inside the container to have nearly the same effect as the steam in the main chamber of the apparatus But for sterilizing empty containers or non-aqueous materials steam pressure sterilization is only suitable provided the containers have porous plugs which allow the free entry of steam But this very fact, while making it easier to attain sterility may make it difficult to maintain it after sterilization is completed. For example, dressings thoroughly sterilized by pressure steam may readily become contaminated if unsterile air is allowed into them either in the sterilizer or afterwards on storage Howie and Timbury (1956) drew attention to the dangers of recontaminating sterilized dressings if non-sterile air is allowed to enter the sterilizer at the end of the process Dressing drums which are intended to overcome the dangers of having dressings in cloth coverings are to be condemned unless their use is very carefully controlled They may reduce the risk of gross contamination or soiling of dressings during storage but they also reduce the efficiency of sterilization since even when the vent holes are open the openings are often too small to allow free passage of steam (Perkins, 1956)

Hot-air sterilization

For certain types of work sterilization by hot air is preferable to pressure steam Hot air has many drawbacks—dry air is much less effective than saturated steam at equivalent temperatures and therefore higher temperatures or longer times have to be used Pocketing of air can be just as troublesome as in pressure steam sterilizers and in some hot air ovens temperature differences of 20 C or more have been recorded in different parts of the same oven at the same time The usual temperature recommended for sterilization of most materials is 160° C for at least 1 hour But as with pressure steam sterilization this time represents a

compromise generally accepted as being safe for all kinds of materials Since many hot air ovens take at least an hour to reach this temperature from cold and also take a long time to cool down the sterilization of one load in a hot-air oven can take anything up to 4–5 hours For really efficient sterilization ovens should be fitted with fans which guarantee an even mixing of hot air (Darmady and Brock, 1954)

Boiling water

It is well known that while immersion in boiling water will kill many vegetative micro-organisms it cannot be relied upon to kill spores in any reasonable time For this reason it should never be relied upon as a routine method of sterilization, especially at high altitudes In an emergency boiling water may have to be used for syringes, syringe needles and instruments but boiled instruments cannot be regarded as necessarily sterile and they should never be described or labelled as such.

Flowing steam

Certain types of articles are " sterilized " by exposure to steam at atmospheric pressure This means that the steam to which they are exposed cannot be at a *temperature higher than 100° C and such articles are not necessarily sterile* Many articles may be usefully disinfected (not sterilized) by exposure to free steam—as, for example bed-pans in the combined bed pan washer and disinfector which uses a steam jet

Other physical agents

Ultra violet irradiation is being widely used for certain types of sterilization It is effective at sterilizing non-porous smooth surfaces, but it has very little penetrating power Even a thin film of dust or moisture may protect micro-organisms from it. It is fashionable to instal ultra violet lamps in rooms, theatres and other places where air contamination is likely to occur There is no doubt that the air of experimental rooms artificially infected with aerosols can be sterilized by ultra violet light It is not so certain that ultra violet irradiation is effective in destroying micro-organisms as they occur naturally in air or in reducing the rates of infection in persons working in such environments In some countries ultra violet lamps have been installed at great expense in theatres, factories and laboratories, but it is still doubtful whether the results justify the expense If ultra violet lamps are used, they must be of the right kind with a high proportion of the radiation omitted in the bactericidal range round 2,537 Å

X-rays and γ-rays

These kill micro-organisms very effectively and differ from ultra violet irradiation in having great penetrating power Gamma rays are being developed for the sterilization of food, but it is doubtful to what extent they will be generally used for the sterilization of surgical equipment.

Infra-red

Infra red irradiation is widely used for many industrial purposes and claims have been made recently that infra red is an effective method for sterilizing syringes

and other equipment · Future developments in this field promise to be of considerable interest (Darmady Hughes and Tuke, 1957)

Central sterilization

There is no doubt that wherever it can be used heat is the best of the sterilizing agents in present-day use, and that of methods of sterilization by heat steam under pressure is the best Heat sterilization however can be relied upon only if the apparatus used is reliable and reliably operated This needs a clockwork routine which is not easy to achieve when it has to be carried out by staff engaged in a variety of other quite different and exacting duties . Dressings may come out of the sterilizer sodden there may be gross overloading, or there may be errors in the times and temperatures of exposure As a result heat sterilization tends to be discarded in favour of apparently simpler methods—for example immersion in disinfectant solutions followed by rinsing.

These difficulties can be overcome only by setting up an efficient central sterilizing service which can provide sterile materials and instruments for all the purposes included in its scope. In Great Britain there is still some opposition to this idea The arguments commonly produced are that it is very expensive, that it deprives nurses and others of a valuable part of their training, that it can be very inconvenient and that emergency methods of sterilizing must still be available in the theatre in case the central supply breaks down Not one of these arguments is sound and they can all be dealt with by intelligent planning and organization Costs are difficult to calculate but presumably it would be less not more, expensive to concentrate sterilization in a central, well-equipped department rather than dissipate the work at several different points (Perkins, 1956) In other countries which have experience of this matter it is said that efficient central sterilization has been proved to save money As regards training, it is surely better to train nurses and others in the proper use of efficient apparatus than to expect them to learn the principles of sterilization from inefficient antiquated apparatus With properly organized central supply departments there should never be any inconvenience Packs of different kinds, sets of instruments to suit each surgeon's taste—all these things can be quite simply and smoothly supplied and the surgeon can rest assured that the equipment and instruments really are sterile up to the moment when they are handed to him. If the organization is efficient the question of emergency supplies in case of a breakdown should never arise because reserve supplies will always be available

A central supply department must be of the right size to be economical Many hospitals stimulated by the fear of litigation for example following syringe-transmitted jaundice, have set up central syringe services, but surgical instruments and equipment are still sterilized in different places This is a bad compromise. A central department to be economic should certainly be capable of handling all the sterile supplies required by the hospital or even perhaps by a group of hospitals.

SOME SPECIAL PROBLEMS

Certain articles present especially awkward problems Rubber gloves do not withstand high temperatures and are usually sterilized at a steam pressure of 5 pounds which would give a temperature of 109° C if all air were removed from

the system Since this is certainly seldom achieved the gloves are actually being treated at a much lower temperature which may even be below 100° C. Air pockets in the fingers of the gloves are also a great problem There may be a reasonable chance that rubber gloves which have been thoroughly cleaned after use will be successfully sterilized at 5 pounds pressure but certainly the methods generally used cannot be relied upon to sterilize gloves which may have been heavily infected perhaps with sporing organisms on a previous occasion. There is great room for improvement both in the materials used for the manufacture of gloves and in the methods of sterilization.

Sharp instruments also present a difficult problem Opinions differ on the relative merits of boiling, dry heat, autoclaving and immersion in chemical disinfectants Properly used, it seems that hot air or autoclaving are the safest. With knives it is best wherever possible to use instruments with disposable blades which need only be used once Syringes are best sterilized by hot air but, as has been mentioned already the temperature must be very carefully controlled

GENERAL CONCLUSIONS

It has been impossible here to do more than touch on a few general principles of sterilization and point out some of the main defects of present day sterilization practice In planning for the future it seems clear that greater care should be taken to secure precision in the methods used, so that sterilization can be more reliable and at the same time less damaging to the materials being sterilized. Efficiency and economy in the long run can be secured only by a comprehensive central sterilizing department. In the planning and operation of this only the closest collaboration between the staff of this department, the engineers and the bacteriologists can give the surgeon the standard of sterilization which he requires

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From inability to let well alone from too much zeal for the new and contempt for what is old from putting knowledge before wisdom science before art and cleverness before common sense from treating patients as cases and from making the cure of the disease more grievous than the endurance of the same Good Lord deliver us New addition suggested for the Litany to be read in hospitals chapels or wherever doctors and nurses do or ought to congregate

ROBERT HUTCHISON

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